

# **Appendix A**

## **Request from Legislature**



May 31, 2019

John Wiesman, Secretary  
Washington State Department of Health  
P.O. Box 47890  
Olympia, Washington 98504-7890

Dear Secretary Wiesman,

I am requesting that the Department of Health consider a Sunrise Review application for a proposal that would change the scope of practice for acupuncturists, including increasing approved Point Injection Therapy injectables, clarifying substance use disorder treatments, and providing for the practice of dry needling.

A copy of the proposal is attached and my office can provide you with the H-draft number once it has been processed by the Office of the Code Reviser. The House Health Care and Wellness Committee would be interested in an assessment of whether the proposal meets the sunrise criteria for expanding the scope of practice for a regulated health profession in Washington.

I appreciate your consideration of this application and I look forward to receiving your report. Please contact my office if you have any questions.

Sincerely,

Handwritten signature of Eileen Cody in black ink.

Eileen Cody, Chair  
House Health Care and Wellness Committee

Cc: Kelly Cooper, Washington State Department of Health  
Leslie Emerick, Washington East Asian Medicine Association  
Kim Weidenaar, Office of Program Research

## **Appendix B**

### **Bill Draft**

AN ACT Relating to acupuncture;

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

**Sec. 1.** RCW 18.06.010 and 2016 c 97 s 1 are each amended to read as follows:

The following terms in this chapter shall have the meanings set forth in this section unless the context clearly indicates otherwise:

(1) "Acupuncture" or "Eastern medicine" means a (~~health care service utilizing acupuncture or Eastern medicine diagnosis and treatment to promote health and treat organic or functional disorders and includes the following~~) holistic system of medicine often referred to as traditional Chinese medicine, Eastern medicine, and other terms, which includes a variety of traditional and modern therapeutic treatments including, but not limited to, the practice of acupuncture techniques and herbal medicine, to maintain and promote wellness, prevent, manage, and reduce pain, treat substance use disorder, and diagnose and treat disease. Acupuncture or Eastern medicine includes:

(a) (~~Acupuncture, including the~~) Use of presterilized, disposable needles, such as filiform needles, and other acupuncture

needles, syringes, or lancets to directly and indirectly stimulate meridians and acupuncture points, including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other non-specific points throughout the body(~~meridians~~);

(b) Use of electrical, mechanical, or magnetic devices to stimulate meridians and acupuncture points, including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other non-specific points throughout the body (~~meridians~~);

(c) All points and protocols for ear acupuncture including, auricular acupuncture, national acupuncture detoxification association protocol, battlefield acupuncture, and the Nogier system;

(d) Use of contact needling and noninsertion tools such as teishin, enshin, or zanshin;

(e) Moxibustion;

~~((d))~~ (f) Acupressure;

~~((e))~~ (g) Cupping;

~~((f))~~ (h) Dermal friction technique;

~~((g))~~ (i) Infra-red;

~~((h))~~ (j) Sonopuncture;

~~((i))~~ (k) Laserpuncture;

~~((j))~~ (l) Point injection therapy, as defined in rule by the department. Point injection therapy includes injection of substances, limited to saline, sterile water, herbs, minerals, vitamins in liquid form, (~~and~~) homeopathic and nutritional substances, and local anesthetics consistent with the practice of acupuncture or Eastern medicine. An acupuncturist or acupuncture and Eastern medicine practitioner using point injection therapy who has met the training and education requirement established in rule may use local anesthetics, oxygen, and epinephrine for potential emergency purposes for patient care and safety. Point injection therapy does not include injection of controlled substances contained in Schedules I through V of the uniform controlled

substances act, chapter 69.50 RCW or steroids as defined in RCW 69.41.300;

~~((k))~~ (m) Dietary advice and health education based on acupuncture or Eastern medical theory, including the recommendation and sale of herbs, vitamins, minerals, and dietary and nutritional supplements;

~~((l))~~ (n) Breathing, relaxation, and Eastern exercise techniques;

~~((m))~~ (o) Qi gong;

~~((n))~~ (p) Eastern massage and Tui na, which is a method of Eastern bodywork, characterized by the kneading, pressing, rolling, shaking, and stretching of the body and does not include spinal manipulation; and

~~((o))~~ (q) Superficial heat and cold therapies.

(2) "Acupuncturist" or "acupuncture and Eastern medicine practitioner" means a person licensed under this chapter.

(3) "Department" means the department of health.

(4) "Secretary" means the secretary of health or the secretary's designee.

Nothing in this chapter requires individuals to be licensed as an acupuncturist or Eastern medicine practitioner in order to provide the techniques and services in subsection (1) ~~((k))~~ (m) through ~~((o))~~ (q) of this section or to sell herbal products.

**Sec. 2.** RCW 18.06.230 and 2016 c 97 s 4 are each amended to read as follows:

(1) Prior to providing point injection therapy services, an acupuncturist or acupuncture and Eastern medicine practitioner must obtain the education and training necessary to provide the service.

(2) Any acupuncturist or acupuncture and Eastern medicine practitioner performing point injection therapy prior to June 9, 2016, must be able to demonstrate, upon request of the department of

health, successful completion of education and training in point injection therapy.

(3) Prior to administering local anesthetics, epinephrine, or oxygen in providing point injection therapy services, an acupuncturist or acupuncture and Eastern medicine practitioner must obtain the education and training necessary to provide these substances. The department shall adopt rules by July 1, 2021, to specify the education and training necessary to administer local anesthetics, oxygen, and epinephrine.

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## **Appendix C**

### **Applicant Report and Follow Up**

## Washington State Department of Health Sunrise Review

### Proposal to Increase Scope of Practice for Acupuncture and Eastern Medicine (Name Change effective 7/28/19, SHB 1865, 2019 Legislative Session)

#### Applicant Cover Sheet

**Legislative proposal being reviewed under the sunrise process:** Scope clarification and expansion originally proposed in HB1865 (2019 session), now DRAFT HB ----- with some minor changes. (Bill Draft Submitted by Representative Cody 5/30/19, with letter to John Wiesman, Secretary of Health)

**Name and title of profession the applicant seeks to credential:**

Title: Acupuncture and Eastern Medicine: SHB 1865 (formerly East Asian Medicine)

Acupuncture and Eastern Medicine Practitioners (AEMP)

East Asian Medicine Practitioner (EAMP)

Acupuncturists (L.Ac.)

**Approximate number of individuals practicing in WA state:**

There are currently 1,599 active licensed East Asian medicine practitioners in Washington. Of this total, 115 are located out of state.

**Information about applicant's organization:**

Washington Acupuncture and Eastern Medicine Association (WAEMA) is the primary organization representing acupuncturists in Washington State through advocacy and educational efforts.

**Contact:**

Charis Wolf, WAEMA President

2311 N 45th Street, #337

Seattle WA 98103

Business: 360-830-6453/Cell: 415-412-1585

[C.Wolf@weama.info](mailto:C.Wolf@weama.info)

Leslie Emerick, WAEMA Lobbyist

[Lesemerick@lkemerick.com](mailto:Lesemerick@lkemerick.com)

360-280-6142

**Number of members in the organization:** approximately 280 members

**Names & addresses of national organizations with which the state organization is affiliated:**

**American Society of Acupuncturists (ASA)**

4400+ members

David Miller (Chair)

4361 N Lincoln, Ave, unit 5

Chicago, IL 60618

Ph: 773-960-8901

**National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM)**

17,653 Board Certified Acupuncturists

2025 M St NW, Ste 800

Washington DC, 20036

Ph: 888-381-1140, 202-381-1140

**Name of other state or national organizations representing the profession:**

None

**States that regulate this profession:**

47 states have some form of regulation over the practice of acupuncture, 3 do not. These states have regulations that will include the scope expansion that the profession seeks: Florida, New Mexico, Colorado, South Carolina, Utah, Washington

**This proposal will be divided into two sections: Clarification of existing scope and expansion of existing scope:**

**Clarification of Existing Scope:**

1. **Define the problem and why the change in regulation is necessary (refer to RCW 18.120.030(1)).** The definition of what is considered acupuncture is not clear enough for the general public and additional clarification is needed to assure that citizens understand the depth and breath of the practice of acupuncture. The problem is that there is currently confusion over the insertion of acupuncture (filiform) needles for therapeutic purposes with other professions using different terminology for the same procedures used by licensed acupuncturists in Washington state. RCW 18.120.030 states that:

(a) The nature of the potential harm to the public if the health profession is not regulated, and the extent to which there is a threat to public health and safety;

(b) The extent to which consumers need and will benefit from a method of regulation identifying competent practitioners, indicating typical employers, if any, of practitioners in the health profession;

The potential harm to the public is when practitioners are not adequately trained or licensed to practice acupuncture in the state and the consumer becomes confused about what kind of treatment they are receiving and whether it is by a licensed practitioner with the treatment (acupuncture) within their scope of practice.

This is not intended to limit other professions from gaining access to acupuncture techniques legislatively with appropriate training, it only assures that these terms will also be understood as the practice of acupuncture, not to be superseded or disallowed by alternative definitions that may arise in the future.

To address this problem, we request a clarification in our scope of practice around what is considered acupuncture with the following language:

- a) (a) ((Acupuncture, including the )) Use of presterilized, disposable needles, such as filiform needles, and other acupuncture needles, syringes, or lancets to directly and indirectly stimulate meridians and acupuncture points, including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other non-specific points throughout the body.
- b) (b) Use of electrical, mechanical, or magnetic devices to stimulate meridians and acupuncture points, including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other non-specific points throughout the body. (See attached Exhibit A for a) and b).)

Ashi points and trigger points are already defined under the current East Asian Medicine Practitioner, WAC 246-803-030 (10)(b) which states “For the purposes of this section, includes trigger points as a subset of acupuncture points and Ashi points as recognized in the current practice of East Asian medicine.” This needs to be clarified in our scope of practice as well to prevent confusion by the general public regarding the practice of acupuncture.

**Auricular or Ear Acupuncture** has always been in the scope of practice for acupuncture as it is just another part of the body that practitioners treat. Due to the popularity of the procedure nationally with the Veteran’s Administration for reduction of anxiety, reduction of cravings and stress, often related to PTSD, and the opioid epidemic, we request that auricular acupuncture and the associated protocols be specifically identified to assure that the public clearly understands that this is a form of acupuncture regulated by the Washington State Department of Health. (See attached Exhibit B)

- c) All points and protocols for ear acupuncture including auricular acupuncture, national acupuncture detoxification association protocol, battlefield acupuncture, and the Nogier system;

The stimulation of the acupuncture and Ashi points, either through insertion of needles or contacting the skin with non-inserting tools is also an existing form of acupuncture treatment. Non-inserting techniques still provide the benefit of acupuncture and are commonly used for children or other sensitive individuals who may have a low tolerance for needle insertion. (See attached Exhibit C)

- d) Use of contact needling and non-insertion tools that include but are not limited to teishin, enshin, zanshin.

**2. Explain how the proposal addresses the problem and benefits the public (refer to RCW 18.120.030(4)).** RCW 18.120.030 requires that the public and consumers clearly understand the profession and the treatments that they provide under state law. Other professions using acupuncture (filiform) needles therapeutically are practicing acupuncture under a different name causing confusion for the public. We want to assure that any use of acupuncture (filiform) needles for therapeutic purposes is considered acupuncture under the law. Public safety could be at risk with unauthorized use of acupuncture (filiform) needles, coupled with inadequate training and potentially operating outside of their scope of practice.

**3. What is the minimum level of education and training necessary to perform the new skill or service based on objective criteria?** All of the requested language changes above are already covered in master's level training provided by Washington states' approved acupuncture schools such as Bastyr University and others. The education ranges from 1,500 hours minimum to over 2,000 hours of training depending on the area of focus within the acupuncture and Eastern Medicine profession. A licensed acupuncturist must pass the NCCAOM board certification to practice in WA State.

**4. Explain how the proposal ensures practitioners can safely perform the new skill or service (refer to RCW 18.120.030(1) and (4)).** The objective is to clarify these terms in our definitions for acupuncture under RCW 18.06 to reduce confusion and clarify existing scope of practice. All licensed acupuncturists in Washington state must be board certified by the NCCAOM to be able to practice any of the techniques listed above and must be licensed by the state of Washington.

The benefit to the public if regulation is granted is the clarification and reduction of confusion for consumers who are unable to tell what is considered acupuncture treatments by a licensed health care practitioner with acupuncture in their scope of practice. This will assure that the public can identify qualified practitioners; thus, reducing the chance of injury by unqualified practitioners.

**5. Explain how the current education and training for the health profession adequately prepares practitioners to perform the new skill or service (refer to RCW 18.120.030(4)). Address the nature and duration of the education, training, and continuing education, including Washington curricula and accredited/approved out-of-state programs. Be specific on course content and credits/length applicable to the proposal:** The clarifications above are not new skills or services for licensed acupuncturists in WA State, only clarifications of existing scope of practice.

All of the requested language changes above are already covered in master's level training provided by Washington states' approved acupuncture schools such as Bastyr University and others. The education ranges from 1,500 hours minimum to over 2,000 hours of training depending on the area of focus within the acupuncture and Eastern Medicine profession. A licensed acupuncturist must be board certified with the NCCAOM to practice in WA State.

**6. Is an increase in education and training necessary? If so, are the approved educational institutions prepared to incorporate the increase?** No increase in training is required for the improved clarity related to our existing scope of practice. The practitioner is required under the Uniform Disciplinary Act to have the appropriate training to practice any of the treatments listed above.

**7. How does the proposal ensure that only qualified practitioners are authorized to perform the expanded scope of practice?** By clarifying what is considered acupuncture, this should ensure that only qualified practitioners are authorized to perform acupuncture in Washington state.

**8. If there are other factors in RCW 18.120.030 relevant to the proposal, please address them in detail.** In the bill draft is the inclusion of "treating substance use disorder" under the definition of acupuncture or Eastern medicine. This is an additional clarification that acupuncture is considered a non-pharmacological approach towards easing symptoms associated with chemical dependency or substance use disorder for the treatment of pain, anxiety, depression, cravings and other related symptoms. Rules adopted by the Office of the Insurance Commissioner reflects this under the Essential Health benefits rule, WAC 284-43-5640 5 (a)(vi) Acupuncture treatment visits without application of the visit limitation requirements, when provided for chemical dependency and cravings related to substance use disorder. (Please see Exhibits I, I.1, I.2, I.3, I.4, I.5)

### **Expansion of Existing Scope of Practice**

1. **Define the problem and why the change in regulation is necessary (refer to RCW 18.120.030(1)).** The problem is that our current statute, RCW 18.06.010 (1), list of approved substances for Point Injection Therapy (PIT) doesn't include local anesthetics, epinephrine and oxygen which are commonly used for PIT and part of the training curriculum for a practitioner approved to provide this treatment. A change in the regulation is needed to include these

substances that will provide for the comfort and safety of patients receiving this treatment as well as match the education that the practitioners are receiving for the practice of PIT.

Adding these substances will provide patients of acupuncture and Eastern medicine practitioners access to the same substances as are used by other practitioners (physicians, nurse practitioners, naturopaths, physician assistants) who perform trigger point or point injection therapy. (Please see Exhibit D.1, D.2, D.3)

To address this problem, we request a change in our scope of practice to include the following language:

(j) (l) Point injection therapy as defined in rule by the department. Point injection therapy includes injection of substances, including sterile saline, sterile water, herbs, minerals, vitamins in liquid form, and homeopathic and nutritional substances, and local anesthetics consistent with the practice of acupuncture or Eastern medicine. An acupuncturist or acupuncture and Eastern medicine practitioner using point injection therapy who has met the training and education requirement established in rule may use local anesthetics, oxygen and epinephrine for potential emergency purposes for patient care and safety.

- a) **Local anesthetic** is a substance used to temporarily numb a small area of the body and are not considered Controlled Substances in Schedule I-V. Local anesthetic use is standard practice in Point Injection Therapy and is used to help numb the pain of certain injections of allowable substances under RCW 18.06.010 (j) for the comfort of the patient. Local anesthetics are currently being used by primary care providers, naturopaths, dental hygienists, midwives and in long-term care facilities by certified nursing assistants through nurse delegation. (See Exhibit D above)
- b) **Epinephrine** is an injected substance commonly used to treat allergic reactions such as anaphylaxis. Currently acupuncturists (East Asian Medicine Practitioners-EAMP) are allowed to use an epinephrine injection in the form of an EpiPen autoinjector in RCW 70.54.440. (WAC 246-803-040 Education and training for point injection therapy: 2-hour EpiPen training already required) We are requesting that epinephrine for intramuscular injection be added to the list of injectable substances in statute. (See Exhibit D above)

The cost of EpiPens has skyrocketed in recent years and they have a relatively short shelf life. Being able to purchase epinephrine directly from approved wholesale manufactures would make the cost more viable for practitioners to be able to stock this substance and have available in case of emergency. The current WAC requires the epinephrine training but does not require that a practitioner must keep it available in their practice. Current requirements for storing and maintaining EpiPens is cost prohibitive for most EAMPs.

- c) **Oxygen (O2)** is commonly used for patient care and safety to treat allergic reactions, needle

shock and along with epinephrine use, is currently offered in PIT training. Under the current law, if an EAMP wishes to have O2 in their office, a prescription from a primary care provider must be obtained. This is a hardship that is unnecessary. Like the EpiPen, training must be obtained, but neither the EpiPen or O2 in the office is required in order to perform PIT. (See Exhibit D above)

**2. Explain how the proposal addresses the problem and benefits the public (refer to RCW 18.120.030(4)).**

- a) Local anesthetics are commonly used by acupuncturists who are legally authorized to perform PIT and other health care practitioners to manage minor pain that may accompany an injection for a patient. This will benefit the public by allowing a measure of comfort for the patients receiving PIT treatments when appropriate.
- b) This proposal increases public safety by adding oxygen and epinephrine to the list of substances to be used to treat responses that could be associated with PIT. The benefit to the public is that the response time to address an allergic reaction could be lifesaving for a patient.
- c) Adding these substances will provide patients of acupuncture and Eastern medicine practitioners access to the same substances as are used by other practitioners (physicians, nurse practitioners, naturopaths, physician assistants) who perform trigger point or point injection therapy. (See Exhibit D.1 above)

An EAMP will still be required to initiate an emergency response to an allergic reaction under RCW 18.06.140 Consultation with other health care practitioners—Patient waiver—Emergencies—Penalty, (2) In an emergency, a person licensed under this chapter shall: (a) Initiate the emergency medical system by calling 911; (b) request an ambulance; and (c) provide patient support until emergency response arrives.

The addition of local anesthetics, epinephrine and oxygen will provide patients of Acupuncture and Eastern Medicine practitioners (AEMPs) access to the same substances as are used by other practitioner who perform trigger point or point injection therapy (PIT). They are all a part of modern PIT. (see Exhibit D.1)

Suppliers of injectables for PIT and educators will have a clear sense of what can be used by an AEMP. If the expanded list of approved substances is accepted; the list would be consistent with other states and with the current training that is available. (Please see Exhibit E.1, E.2)

**3. What is the minimum level of education and training necessary to perform the new skill or service based on objective criteria?**

- a) **Local anesthetics:** As part of current Point Injection Therapy (PIT) training nationally, the use of local anesthetics is commonly taught as part of their curriculum in 24-hour training sessions. According to Christina Captain, DAOM who currently teaches PIT classes in WA, local anesthetics are given a minimum of 1.5 hours of lecture and 8 hours of clinical

training. The NCCAOM has programs accrediting PIT trainings. The areas where local anesthetics such as lidocaine or procaine are commonly used are trigger points, tendons, scars and adhesions. They are “points” of tightness, tenderness, or discomfort anywhere in the body that may affect movement and normal function, or the quality of life of people affected by them. (Exhibit F.1, F.2, F.3)

**b) Epinephrine and Oxygen:** Regarding training in the use of epinephrine and oxygen, of the 24 hours that the DOH requires before performing PIT, up to 2 hours is required for the use of epinephrine. There is ample time within that 2 hours to teach the safe use of epinephrine and oxygen in a clinical setting. (Please see Exhibit G.1, G.2, G.3)

**4. Explain how the proposal ensures practitioners can safely perform the new skill or service (refer to RCW 18.120.030(1) and (4)).** We believe that we can ensure that practitioners can perform the new skill or service listed above in question #3 in addition to the current training required in WAC 246-803-040 Education and training for point injection therapy listed below:

**WAC 246-803-040: East Asian medicine practitioners employing point injection therapy shall use only those substances and techniques for which they have received training.**

(1) The education and training for point injection therapy must:

(a) Consist of a minimum total of twenty-four contact hours of training in the topics required in this section;

(b) Include at least eight hours of clinical practical experience; and

(c) Be administered by an instructor that meets the requirements of subsection (4) of this section.

(2) A curriculum for a point injection therapy training program must include:

(a) Review of physical examination, contraindications and universal precautions, and differential diagnosis;

(b) Compounding and administration of the substances authorized for point injection therapy under WAC 246-803-030, including aseptic technique, recordkeeping and storage of substances authorized for use in point injection therapy;

(c) Emergency procedures;

(d) Point injection therapy techniques and contraindication within the East Asian medicine scope of practice relative to the authorized substances listed in WAC 246-803-030 (10)(a)(i) through (vi).

(3) Except for the training in the use of intramuscular epinephrine, the training must be delivered in person and not through webinar or other online or distance learning method.

(4) An instructor for point injection therapy must have:

(a) A health care credential in good standing with a scope of practice that includes point injection therapy; and

(b) At least five years of experience in a health care practice that includes point injection therapy.

(5) In addition to point injection therapy meeting the requirements of subsections (1) and (2) of this section, East Asian medicine practitioners using point injection therapy must complete training in the use of intramuscular epinephrine.

(a) Training in the use of intramuscular epinephrine must be according to RCW [70.54.440\(4\)](#).

(b) This training may be taken separately from the training in point injection therapy.

(c) Up to two hours of training in the use of intramuscular epinephrine count in meeting the requirement for twenty-four hours of training.

(d) An East Asian medicine practitioner who holds an active credential with a scope of practice that includes the authority to prescribe, dispense or administer epinephrine does not need to meet the requirements of (a) of this subsection.

(6) To qualify under this section, the training program shall provide each successful student with a:

(a) Certificate of successful completion of the program; and

(b) Course syllabus outlining the schedule and curriculum of the program.

(7) The requirements of subsections (1) through (6) of this section do not apply to an East Asian medicine practitioner who has provided point injection therapy prior to July 1, 2017. East Asian medicine practitioners using point injection therapy prior to July 1, 2017, must have completed training and education in point injection therapy.

(8) Any East Asian medicine practitioner performing point injection therapy must be able to demonstrate, upon request of the department of health, successful completion of education and training in point injection therapy.

**5. Explain how the current education and training for the health profession adequately prepares practitioners to perform the new skill or service (refer to RCW 18.120.030(4)). Address the nature and duration of the education, training, and continuing education, including Washington curricula and accredited/approved out-of-state programs. Be specific on course content and credits/length applicable to the proposal:**

All practitioners in WA state must first pass the board certified NCCAOM exams which adequately prepare them to perform the services with the additional training.

**a) Local anesthetics:** As part of current Point Injection Therapy (PIT) training nationally, the use of local anesthetics is commonly taught as part of their curriculum in 24-hour training sessions. According to Christina Captain, DAOM who currently teaches PIT classes in WA, local anesthetics are given a minimum of 1.5 hours of lecture and 8 hours of clinical training. The NCCAOM has programs accrediting PIT trainings. The areas where local anesthetics such as lidocaine or procaine are commonly used are trigger points, tendons, scars and adhesions. They are “points” of tightness, tenderness, or discomfort anywhere in the body that may affect movement and normal function, or the quality of life of people affected by them. (See Exhibit F.1, F.2, F.3)

**b) Epinephrine and oxygen:** Regarding training in the use of Epinephrine and Oxygen, of the 24 hours that the DOH requires before performing Point Injection Training, up to 2

hours is required for the use of Epinephrine. There is ample time within that 2 hours to teach the safe use of epinephrine and oxygen in a clinical setting. (See Exhibit G.1, G.2, G.3)

6. **Is an increase in education and training necessary? If so, are the approved educational institutions prepared to incorporate the increase?** Yes, an increase in training is necessary for the use of the substances proposed in the scope expansion and would be required under WAC 246-803-040. Currently there are a number of NCCAOM approved educational institutes providing necessary education and training for PIT that includes local anesthetics, oxygen and epinephrine within the 24 hours required. (See Exhibit F.2, F.3, G.1, G.2)
7. **How does the proposal ensure that only qualified practitioners are authorized to perform the expanded scope of practice?** WAC 246-803-040 Education and training for point injection therapy clearly states that East Asian medicine practitioners employing point injection therapy shall use only those substances and techniques for which they have received training. The new substances would be enforceable under this WAC.

**The new language proposed in the bill draft also includes training requirements:**

Section 2 (3) Prior to administering local anesthetics, oxygen and epinephrine in providing point injection therapy services, an acupuncturist or acupuncture and Eastern medicine practitioner must obtain the education and training necessary to provide these substances. The department shall adopt rules by July 1, 2021, to specify the education and training necessary to administer local anesthetics, oxygen and epinephrine.

8. **If there are other factors in RCW 18.120.030 relevant to the proposal, please address them in detail.** (Please see additional research articles in Exhibit H.1, H.2, H.3, H.4, H.5, H.6, H.7, H.8)

## 2019 Acupuncture Scope of Practice Sunrise Follow Up Questions on Applicant Report

1. Please elaborate on how oxygen is administered during point injection therapy.
  2. Please provide details on the training provided on the use of oxygen.
  3. With the increased risk of an allergic reaction during point injection therapy, should oxygen and epinephrine be required in the offices of acupuncturists that practice point injection therapy?
- 
1. **Emergency oxygen** is delivered from a cylinder, through a pressure regulator and **oxygen** tubing, and delivered via a mask.
  2. **Safety training:** The management of anaphylaxis and associated emergency protocol is taught during the required 24 hours of training before performing PIT. There is ample time within the 2 hours safety training requirement to teach the safe use of epinephrine and emergency oxygen in a clinical setting.
  3. No state that allows PIT requires in office oxygen and epinephrine. We request that it remain optional in WA State.

## Page Numbers for Applicant Report Exhibits

- Exhibit A.1 A-21
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- Exhibit H.7 A-95
- Exhibit H.8 A-97
- Exhibit I A-100
- Exhibit I.1 A-105
- Exhibit I.2 A-107
- Exhibit I.3 A-128
- Exhibit I.4 A-202 (document is nearly 500 pages long so just a link is included here)
- Exhibit I.5 A-203

## Exhibit A.1

Evidence that this terminology is a part of acupuncture and is practiced broadly by our profession in the state and the country:

Intramuscular Stimulation (IMS);  
(from the Gunn/IMS website)

IMS relies heavily on a thorough physical examination of the patient by a competent practitioner, trained to recognize the physical signs of neuropathic pain. This physical examination is indispensable since chronic pain is often neurological as opposed to structural, and therefore, invisible to expensive X-rays, MRI Tests, Bone and CT Scans. Failure to recognize these signs will result in an inaccurate diagnosis, and thus, a poor starting point for physical therapy. The treatment involves dry needling of affected areas of the body without injecting any substance. The needle sites can be at the epicenter of taut, tender muscle bands, or they can be near the spine where the nerve root may have become irritated and supersensitive. Penetration of a normal muscle is painless; however, a shortened, supersensitive muscle will 'grasp' the needle in what can be described as a cramping sensation. The result is threefold. One, a stretch receptor in the muscle is stimulated, producing a reflex relaxation (lengthening). Two, the needle also causes a small injury that draws blood to the area, initiating the natural healing process. Three, the treatment creates an electrical potential in the muscle to make the nerve function normally again. The needle used in IMS, by stimulating muscle spindles, essentially becomes a specific and unique tool for the diagnosis of Neuropathic Muscle Pain.

1) In this first article, it is stated,

"Furthermore, because neural dysfunction occurs as the result of radiculopathy, a prime purpose of IMS treatment is to relieve shortening in paraspinal muscles that entraps the nerve root and perpetuates pain."

<https://www.icmart.org/events/archive-icmart-congresses/icmart-congress-2002-edinburgh-scotland/treating-neuropathic-pain-with-ims.html>

2) We in the field of acupuncture know that the Hua Tuo Jia Ji points stimulate the paraspinal muscles and deep nerve roots. These are attributed to a physician living between 110-207 AD. This link shows how they correspond with nerve root pathways. Incidentally, I learned this in school in the late 90s and have also attached the chart that I've had on my desk for 20 years. [https://theory.yinyanghouse.com/theory/tamhealing/huatuo\\_jiaji\\_system](https://theory.yinyanghouse.com/theory/tamhealing/huatuo_jiaji_system)

3) Finally, we can prove that Gunn's initial work that eventually became known as IMS began with acupuncture inquiry. See reference 1 below. From our previous Sunrise rebuttal: "[Chan Gunn, MD] **Gunn's early work was based on trying to find a modern understanding and presentation for acupuncture.** He then developed IMS and began teaching IMS

(Intramuscular Stimulation) i.e. “dry needling.”<sup>1</sup> Gunn stated, “It is suggested that, as a first step towards the understanding and acceptance of acupuncture by the medical profession, the present anachronistic systems of acupuncture locus nomenclature be dispensed with in favour of a modern, scientific one using neuroanatomic descriptions.”<sup>2</sup> It was a rebranding of acupuncture.”

<sup>1</sup> GunnIMS: Intramuscular Stimulation. <http://www.istop.org/ims.html>

<sup>2</sup> Gunn, CC, Ditchburn, F, King, MH, Renwick, GJ. Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Know Neural Structures. *The American Journal of Chinese Medicine* 1976;4(2):183–195.

Chart showing neural connections to vertebra which correspond to the Hua Tou Jia Ji points all along either side of the spine:



## Dry Needling (DN);

"Trigger point needling (aka dry needling) is not new in the practice of acupuncture. Modern acupuncturists use trigger, motor points, and modern anatomy and physiology in their practices. In addition to the default understanding that most of the classical points are in fact trigger points, and that by extension, acupuncturists can be said to be needling trigger points on a daily basis, the majority of acupuncturists incorporate the understanding and treating of trigger and motor points, as trigger and motor points, into their practices. In 2003, the national certifying body for acupuncture standards, the National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM), which administers board exams and board certification, surveyed then-current use of trigger and motor points among acupuncturists. Fully 82% of those acupuncturists surveyed reported the use of trigger points in the treatment of pain."<sup>89</sup>

Additionally, the application attempts to cast doubt that trigger points were ashi points. Although previously submitted in written testimony, the following is worth repeating:

- Ronald Melzack, Ph.D., world-renowned pioneer in the field of pain research, reported that, "trigger points and acupuncture points for pain [i.e. ashi points], though discovered independently, and labeled differently, represent the same phenomenon and can be explained in terms of the same neural mechanisms."<sup>90</sup>
- In describing needling trigger points, L. Kalichman, a physical therapist, and S. Vulfson, a medical doctor, state that a "very similar method was developed in 7th century by Chinese physician Sun Su-Mo [Sun Simiao], who inserted needles at points of pain, which he called Ah-Shi [ashi] points. From the description of these points, it is clear that they are what are currently referred to as MTrPs [Myofascial Trigger points]."<sup>91</sup>
- In 2008, two medical doctors, Dorsher and Fleckenstein, demonstrated that 93.3% of the "common trigger points" in Travell's Trigger Point
- Manual corresponded anatomically to established classical, channel-based acupuncture points.<sup>92</sup>
- Citing further pain and somatovisceral evidence, they conclude that trigger points and acupuncture points are likely the same physiologic phenomenon.<sup>93</sup>
- The World Health Organization defines trigger points as a subset of acupuncture points.<sup>94</sup>

<sup>89</sup> Fabrey, L, Cogdill, K, Kelley, J. A National Job Analysis: Acupuncture and Oriental Medicine Profession. Olathe, Kansas: Applied Measurement Professionals, Inc.; 2003. [http://www.nccaom.org/wp-content/uploads/pdf/NCCAOM\\_final\\_JA\\_Report\\_2003.pdf](http://www.nccaom.org/wp-content/uploads/pdf/NCCAOM_final_JA_Report_2003.pdf).

<sup>90</sup> Melzack, R, Stillwell, DM, Fox, EJ. Trigger Points and Acupuncture Points for Pain: Correlations and Implications. *Pain*. 1977;3(1):3–23.

91 Kalichman L, Vulfsons S. Musculoskeletal Pain, Journal of the American Board of Family Medicine 2010; 23(5): 640-646.

92 Dorsher PT, Fleckenstein J. Trigger Points and Classical Acupuncture Points, Part 1: Qualitative and Quantitative Anatomic Correspondences. German Journal of Acupuncture and Related Techniques 2008;51(3): 15-24.

93 Ibid. 94

95 On the Probability of Trigger Point–Acupuncture Point Correspondences: An Evidence-Based Rebuttal of

Links:

<http://www.asacu.org/wp-content/uploads/2019/03/Dry-Needling-is-Acupuncture-McIntyre-A.pdf>

<http://www.asacu.org/wp-content/uploads/2018/09/ASA-Acupuncture-and-Dry-Needling-Myth-Versus-Fact-2018.pdf>

<https://www.nccaom.org/about-us/press/press-releases/aapmr-policy-on-dry-needling/>

### ***American Medical Association Policy on Dry Needling H-410.949<sup>1</sup>***

*Our AMA recognizes dry needling as an invasive procedure and maintains that dry needling should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists.*

*“Dry needling is indistinguishable from acupuncture.”<sup>2</sup>*

## HOT TOPIC

### Evidence and Expert Opinions: Dry Needling versus Acupuncture ( II )

—The American Alliance for Professional Acupuncture  
Safety (AAPAS) White Paper 2016

FAN Arthur Yin<sup>1,2</sup>, XU Jun<sup>1,3</sup>, and LI Yong-ming<sup>1,3</sup>

**ABSTRACT** In the United States and other Western countries, dry needling has been a topic in academic and legal fields. This White Paper is to provide the authoritative information of dry needling versus acupuncture to academic scholars, healthcare professionals, administrators, policymakers, and the general public by providing the authoritative evidence and expertise regarding critical issues of dry needling and reaching a consensus. We conclude that Dr. Travell, Dr. Gunn, Dr. Baldry and others who have promoted dry needling by simply rebranding (1) acupuncture as dry needling and (2) acupuncture points as trigger points (dry needling points). Dry needling simply using English biomedical terms (especially using "fascia" hypothesis) in replace of their equivalent Chinese medical terms. Dry needling is an over-simplified version of acupuncture derived from traditional Chinese acupuncture except for emphasis on biomedical language when treating neuromuscular-skeletal pain (dry needling promoters redefined it as "myofascial pain"). Trigger points belong to the category of Ashi acupuncture points in traditional Chinese acupuncture, and they are not a new discovery. By applying acupuncture points, dry needling is actually trigger point acupuncture, an invasive therapy (a surgical procedure) instead of manual therapy. Dr. Travell admitted to the general public that dry needling is acupuncture, and acupuncture professionals practice dry needling as acupuncture therapy and there are several criteria in acupuncture profession to locate trigger points as acupuncture points. Among acupuncture schools, dry needling practitioners emphasize acupuncture's local responses while other acupuncturists pay attention to the responses of both local, distal, and whole body responses. For patients' safety, dry needling practitioners should meet standards required for licensed acupuncturists and physicians.

**KEYWORDS** dry needling, acupuncture, trigger points, acupuncture points, invasive therapy, evidence, expertise, consensus

#### Does Dry Needling Use Acupuncture Points?

##### Evidence

Dry needling (DN) is based on using dry needles (i.e. filiform, hypodermic hollow-core needles, or other injection needles) to pierce and stimulate trigger points (TrPs).<sup>(8,13,14,36)</sup>

Dr. Travell and her colleagues<sup>(13)</sup> systematically summarized 255 TrPs in 144 muscles in her popular book, titled *Myofascial Pain and Dysfunction: Trigger Point Manual*, thus, popularizing TrPs and DN. TrPs, the reactive (painful) points that are not completely fixed in muscle bellies,<sup>(8,13,14)</sup> are described as "hyperirritable spots in the fascia surrounding skeletal muscle". They are associated with palpable nodules in taut bands of muscle fibers. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena. Dr. Travell admitted to

the general public that DN is acupuncture when she stated in a newspaper that "the medical way of saying it is 'acupuncture.' In our language that means sticking a needle into somebody."<sup>(37)</sup> and in her book, "many practitioners of acupuncture use several TrP criteria to locate pain acupuncture points and, in fact, are successfully performing dry needling of TrPs that they speak of as acupuncture therapy".<sup>(13)</sup>

Dommerholt,<sup>(3)</sup> a known physical therapist, wrote:

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"DN is an invasive procedure in which a solid filament needle is inserted into the skin and muscle directly at a myofascial TrP. A myofascial TrP consists of multiple contraction knots, which are related to the production and maintenance of the pain cycle. ... DN also falls within the scope of acupuncture practice. ... In contrast to most schools of acupuncture, DN is strictly based on Western medicine principles and research."

A clinical study by Anderson and colleagues<sup>(38)</sup> shows that TrPs, typical locations of tender points in many patients, were not just soft, but the softest spots in the muscle—the opposite of what most people would expect. "A heterogeneous distribution of pressure pain sensitivity and muscle hardness was found," which indicates TrPs are not necessarily the "tightest" painful spots within muscles.

The *Yellow Emperor's Inner Classic* (Huang Di Nei Jing, which was compiled 2000 years ago)<sup>(32)</sup> first documented the reactive (painful) acupuncture point needling strategy and stated that "the painful point is the site for acupuncture (Yi Tong Wei Shu)."

The term of Ashi point (AKA tender point) was formally coined by Dr. SUN Si-miao (581–682 CE), a famous Chinese physician in the Tang dynasty, for these reactive (painful) acupuncture points.<sup>(35)</sup> He stated that, "In terms of the method of Ashi, in speaking of a person who has a condition of pain, when squeezing [that area], if there is a painful spot inside the patient says, "Ah yes!" Thus, they are called Ashi points."

Gunn, et al<sup>(23)</sup> in 1976 proposed that "as a first step toward acceptance of acupuncture by the medical profession, it is suggested that a new system of acupuncture locus nomenclature be introduced." Gunn and his colleagues started to use the term motor points (TrPs' synonym) as a substitute for the term acupoints in their publication.<sup>(24)</sup>

### Expertise

Melzack and colleagues<sup>(39)</sup> published the first evidence-based study comparing TrPs with classic acupoints in Chinese medicine (CM), which was based on reviewing a set of 56 TrPs, and then they compared these to CM classic acupoints that are primarily used to treat regional pain conditions. They found that all 56 TrPs were within 3 cm of an acupoint,

and that 71% had the same pain indications as those acupoints studied. This close correlation suggests that TrPs and (classic) acupoints for pain, though ... labeled differently, represent the same phenomenon and can be explained in terms of the same underlying neural mechanisms. The discovery of anatomically defined CM acupoints was profound as it provided a physiologic foundation for how acupuncture might work.

Birch<sup>(40)</sup> challenged Melzack's validity of conclusion and investigated the two categories of acupoints through a broader range of literature. In his review, correlated CM acupoints were defined to exhibit pressure pain, and are used primarily for pain problems. His results showed an 18% rather than 71% correspondence of TrPs and CM classic acupoints for the treatment of pain. He further pointed out that TrPs and (classic meridian) acupoints do not fall into same concept category, and believes that a probable correspondence of TrPs to a different class of acupoints, is the Ashi points.

Dorsher and Fleckenstein<sup>(41,42)</sup> applied different criteria than Melzack for anatomic correspondence and they defined that two points are correlated anatomically if they are within a 2-cm radius of each other and entered the same muscle. They investigated 255 common TrPs and compared them with CM classic acupoints. They found that 238 (93.3%) TrPs anatomically corresponded with classical acupoints. Furthermore, if the TrPs which are located internally and thus not fit for needling are eliminated, the corresponding rate will be even higher. They stated that "the marked correspondences of the pain indications (up to 97%) and somatovisceral indications (up to 93%) of anatomically corresponding common TrP- classical acupoints pairs provide a second, clinical line of evidence that TrPs and acupoints likely describe the same physiologic phenomena." Moreover, the myofascial referred-pain patterns of 76% of TrPs accurately followed relevant meridian distributions. In a further study, Dorsher<sup>(43)</sup> reviewed four acupuncture texts (three are different from Birch's selection) to examine the validity of Birch's findings. He suggested that TrPs could conceptually be compared to classic acupoints for pain disorders, and that the clinical correspondence was over 95%.

Zhou, et al<sup>(8)</sup> stated that acupuncture...the

commonly used procedure for musculoskeletal pain involves Ashi points with the treatment protocols similar to those of DN.

Peng, et al<sup>(9,10)</sup> compared TrPs and acupoints, and concluded that TrPs used in DN (in Western) is acupoints, within one category of traditional acupuncture points: the Ashi points (literally, "Ah-yes; this is the needling point" or tender point), widely used by majority acupuncturists.

Zhu and Most<sup>(11)</sup> systematically reviewed DN history, many scholars' works on its origin, the comparisons of TrPs and acupoints, and they concluded that TrPs are exactly acupoints. They stated, "TrPs in DN and acupoints in acupuncture are derived from painful spots or tender/tight nodules. Muscle pain can be relieved effectively when the target points are needled. The same phenomenon is given different names."

Fan, et al<sup>(18,36,44)</sup> commented that Ashi originally means the reactive pain points, or tender points, while TrPs are only tender points found in muscle bellies; therefore, TrPs completely fall within the Ashi points category. TrPs needling has been widely and internationally used in the daily practices of acupuncturists. Based on extensive literature review and clinical experience, Jin, et al<sup>(12)</sup> and Hong, et al<sup>(45)</sup> reached the same conclusion.

Liu, et al<sup>(46)</sup> stated that TrPs are significantly correlated to CM acupoints, including primary channel acupoints, extra acupoints, and Ashi points. TrPs may be considered as a rediscovery of the nature of acupoints, at least for treating pain conditions. Considering the correlation between TrPs and acupoints and the rarely-studied research area involving Ashi points, it may be reasonable to apply the findings of TrPs as a valuable foundation for future investigation into Ashi points. Ashi points might be central or attachment TrPs, and the most significant characteristic of Ashi points may be pain recognition rather than pressure pain.

#### Other Facts

The National Commission for the Certification of Acupuncture and Oriental Medicine, the certifying board for licensed acupuncturists, completed an analysis in 2003 that documented the prevalence

of DN techniques in the practices of licensed acupuncturists. Of acupuncturists responding, 82% used needling of TrPs in patients that presented with pain. Of patients receiving acupuncture treatment, an estimated 56% present with TrPs pain.<sup>(4)</sup>

#### AAPAS Comments

In traditional Chinese acupuncture using classical CM languages and contemporary biomedical languages, there are at least three categories of acupoints,<sup>(33,34)</sup> namely Ashi points, classical meridian acupoints and extra-meridian acupoints. Ashi points commonly include local or distal reactive pain points or called tender points, as well as local foci, local atrophy area, local skin change area, etc. Stimulating such Ashi points is a common strategy in acupuncture for the treatment of (but not limited to) pain due to neuromusculoskeletal and connective tissue disorders, and local and sometimes distal illnesses and disorders. The localization of Ashi is largely dependent on the palpitation and searching by the practitioners; sometime its central point location has some variations in different patients with the same condition or even in same patients in different stages of the condition. Classical CM acupoints include 361 points on 14 major meridians, which can be used to treat both local and distal external and internal illnesses and conditions, including pain. The extra-meridian acupoints include at least 1,655 acupoints, which are not located on 14 major meridians, for the treatments of local issues including pain or even distal illness.<sup>(47)</sup> Both classical meridian acupoints and extra-meridian acupoints are given specific point-names and originally derived from the Ashi points, their locations are relatively clearer, and basically fixed.<sup>(33,34)</sup> Therefore, classical meridian acupoints and extra meridian acupoints largely overlap with Ashi points when treating the neuromuscular-skeletal pain (DN promoters redefined it as "myofascial pain"). An acupoint is not a spot but an area,<sup>(48)</sup> in a real clinical practice, each needling zone ("acuzone") actually represents an area with one or more central points (a zone can be reached by needle horizontally, generally can be a 2–4 cm radius). Thus it is highly likely that acupoints *per se* overlap. TrPs largely overlap with both the classic and extra-meridian acupoints category (except for very few TrPs that are located internally, which are only fitting for manual therapy and not for needling) when treating pain. However, from the definition of TrPs, that they are part of tender points in

muscle bellies (in which their locations are not totally fixed, regardless of whether they have or do not have hard or tight nodules), the tender points are considered part of Ashi points. It can therefore be concluded that TrPs completely fall within Ashi points category.

Definitions from related authors and analyses from independent scholars indicate that, in Western countries, DN does use acupuncture points. TrPs look like a rediscovery of the nature of acupoints, considering that DN has arisen much later than acupuncture (which has had many different schools over time) and DN promoters themselves are either acupuncture professionals or researchers (such as Gunn C, Baldry P, Hong CZ, Ma Y, et al), also, the medical doctors who largely cite acupuncturists' work (such as Travell J, and Simmons D, especially Travell whom is an acupuncture clinical researcher and had involved in planning acupuncture conferences),<sup>(37)</sup> except that they use the term DN to replace acupuncture to support the TrPs hypothesis,<sup>(23,24,18,36,44)</sup> help to reveal the reasons and factors for the start of DN.<sup>(18,36,44)</sup> From all of this, we conclude that DN has resulted from simply rebranding (1) acupuncture as dry needling and (2) acupuncture points as trigger points by simply using English biomedical terms (in "fascia" hypothesis) in place of their equivalent CM terms.

In addition, Dr. Travell admitted to the general public that DN is acupuncture when she stated in a newspaper that "the medical way of saying it is 'acupuncture'. In our language that means sticking a needle into somebody",<sup>(37)</sup> and acupuncture professionals practice DN as acupuncture therapy and there are several criteria in the acupuncture profession to locate TrPs as acupoints.<sup>(13)</sup> Her words are very clear: TrPs are acupoints.

### **What Is New About Dry Needling Points (Trigger Points)?**

#### **Evidence**

Travell and her colleagues<sup>(13)</sup> summarized the TrPs' characteristics in their popular book *Myofascial Pain and Dysfunction: Trigger Point Manual* as: (1) Pain related to a discrete, irritable point in skeletal muscle or fascia, not caused by acute local trauma, inflammation, degeneration, neoplasm or infection; (2) The painful point can be felt as a nodule or band in the muscle, and a twitch response can be elicited on stimulation of the trigger point; (3) Palpation of the

trigger point reproduces the patient's complaint of pain, and the pain radiates in a distribution typical of the specific muscle harboring the trigger point; (4) The pain cannot be explained by findings on neurological examination. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena. Dommerholt<sup>(3)</sup> wrote: "a myofascial TrP consists of multiple contraction knots, which are related to the production and maintenance of the pain cycle."

Chen, et al<sup>(49)</sup> used magnetic resonance elastography (MRE, a modification of existing magnetic resonance imaging equipment to image stress produced by adjacent tissues with different degrees of tension) to image the taut band of a TrP in an upper trapezius muscle and tried to find the cause of myofascial pain symptoms. Their MRE image of the taut band shows the V-shaped signature of the increased tension (50% greater) compared with surrounding tissues. The study suggests that MRE can quantitate asymmetries in muscle tone that could previously only be identified subjectively by examination. In another study with 65 patients<sup>(50)</sup> with myofascial pain with taut bands, the findings suggest that while clinicians may overestimate, and current MRE techniques may underestimate, the presence of taut bands, these bands do exist, can be assessed quantitatively, and do represent localized areas of increased muscle stiffness.

Shah and colleagues<sup>(51)</sup> reported a biochemistry study which compared the tissue at active TrPs, latent TrPs and absent TrPs spots in the trapezius muscle and in normal gastrocnemius muscle, measuring pH, bradykinin, substance P, calcitonin gene-related peptide, tumor necrosis factor alpha, interleukin (IL) 1beta, IL-6, IL-8, serotonin, and norepinephrine, using immunocapillary electrophoresis and capillary electrochromatography, as well as pressure algometry. The results showed that subjects with active TrPs in the trapezius muscle have a biochemical milieu of selected inflammatory mediators, neuropeptides, cytokines, and catecholamines different from subjects with latent or absent TrPs in their trapezius. These concentrations also differ quantitatively from a remote, uninvolved site in the gastrocnemius muscle. The milieu of the gastrocnemius in subjects with active TrPs in the trapezius differs from subjects without active TrPs.

### Expertise

Clinical study by Anderson and colleagues<sup>(38)</sup> shows that TrPs, typical locations of tender points, in many patients, were not just soft, but the softest spots in the muscle—the opposite of what most people would expect. "A heterogeneous distribution of pressure pain sensitivity and muscle hardness was found," which indicates TrPs are not necessarily the "tightest" painful spots within muscles.

Baldry<sup>(22)</sup> indicated that in the West, in 1821 and 1828, Dr. James M. Churchill published the book *A Treatise on Acupuncture*, using the information gathered from Japan and China. Dr. John Elliottson wrote a paper on acupuncture in 1827. "Neither of them employed the complex procedures, techniques, meridian and other theories of traditional Chinese acupuncture as they were trying to avoid the rejection of acupuncture by the medical doctors of the time". Instead, they employed the simplest strategy in acupuncture for the treatment of disease or other conditions—especially neuromusculoskeletal and connective tissue disorders, including musculoskeletal pain—by needling reactive (painful) acupoints (now commonly known as TrPs). This simplest strategy in acupuncture is now commonly known as dry needling.

Gunn, et al<sup>(23)</sup> in 1976 proposed that "as a first step toward acceptance of acupuncture by the medical profession, it is suggested that a new system of acupuncture locus nomenclature be introduced." Gunn and his colleagues started to use the term motor points (TrPs' synonym) as a substitute for the term acupoints in their publication.<sup>(24)</sup>

Jin, et al<sup>(12)</sup> stated that "any modalities, as long as they apply needles to puncture certain locations at the body surface, belong to acupuncture, in spite of how and where the locations of stimulation are determined and whether by either Western neuro-anatomy or CM meridians—the mechanism of DN and acupuncture are one in the same—which achieves the efficacy via neural reflex arcs." "De-meridian (where the meridian theory is not required for acupuncture and other related modalities) is not equivalent to de-acupuncture (modalities derived from but different from acupuncture)···DN has de-meridian attributes but it uses acupuncture needles and techniques; therefore it does not have de-acupuncture attributes. In other words, as long as DN applies filiform needles

to stimulate TrPs, it is in the scope of acupuncture··· to protect the public safety of patients seeking acupuncture, we refute the de-acupuncture claim by DN educators."

### Other Facts

The Council of Colleges of Acupuncture and Oriental Medicine (CCAOM)<sup>(4)</sup> states: "'DN' has resulted in redefining acupuncture and re-framing acupuncture techniques in Western biomedical language. Advancement and integration of medical technique across professions is a recognized progression. However, the aspirations of one profession should not be used to redefine another established profession···It is the position of the CCAOM that these treatment techniques are the de facto practice of acupuncture, not just the adoption of a technique of treatment."

### AAPAS Comments

It is clear that Dr. Travell, Dr. Gunn, Dr. Baldry and others promoted TrPs (DN Points) and DN through re-translating and rebranding acupoints, acupuncture techniques, in one form of biomedical language in "fascia" hypothesis (by removing terminology of traditional Chinese acupuncture) while acupuncture has many different classical and modern schools, including using traditional Chinese acupuncture languages and various biomedical languages. DN is an over-simplified version (or say, simplest version) of acupuncture derived from traditional Chinese acupuncture except for emphasizing biomedical language when treating neuromuscular-skeletal pain (DN promoters redefined it as "myofascial pain"). TrPs belong to the category of Ashi points in traditional Chinese acupuncture, and they are not a new discovery. Among acupuncture schools, DN practitioners emphasize acupuncture's local response while other acupuncturists pay attention to the responses of the local and distal locations, incorporating the whole body.

The "difference" in DN points, or TrPs, is that the studies of TrPs try to focus more on local anatomy (especially hypothesis on "fascia") while former studies of acupuncture extensively focus on the activities of the central nervous system and hormones changes. Travell, et al systematically summarized the 255 myofascial TrPs on 144 muscles, their manual therapies, and needling techniques (under the term

DN, actually TrP acupuncture). It triggers scholars to pay more attentions to the research of local anatomy, biophysics, biochemistry, and imaging of acupoints. Actually there has been more research on the different schools of acupuncture, comparisons among such needling therapies, the relationship among them and the evolution processes of acupuncture globally. It also encourages schools (colleges) of the acupuncture profession to pay more attention to contemporary developments of acupuncture (in different names, terminologies). Acupuncture using biomedical languages is more readily to be accepted by the main medical stream and the general public with Western education background.

However, it is also clear that the four characteristics of TrP mentioned by Dr. Travell are not a consensus of all DN scholars and professionals. The taut band, nodule, or local twitch response are probably not a necessary criteria of a TrP, except TrP is a tender point.<sup>(33,38)</sup>

### **Is Dry Needling a Manual Therapy?**

#### **Evidence**

The Federation of State Boards of Physical Therapy (FSBPT)<sup>(52)</sup> stated that DN is also known as intramuscular manual therapy. Beginning in 2009, the American Physical Therapy Association had recommended the use of the term "intramuscular manual therapy" (IMT) to describe the use of acupuncture needles by physical therapists, however, since late 2011, the organization advocates using dry needling as the term of choice.

A commercial DN educator, Kinetacore,<sup>(53)</sup> explains that "IMT...the easiest way to think of this treatment is to relate it to a massage. The knots in your muscles that massage therapy often targets are similar areas of treatment for IMT (DN). Often times these knots live at a deep level that fingers and hands just can not get to. Those knots are the goal of IMT. The needles used are very fine, thin, and flexible needles that are quickly tapped into the muscle and causes those knots to decrease, the muscle to loosen, and healing to begin which ultimately decreases pain and increases proper function."

Dommerholt<sup>(3)</sup> wrote: "DN is an invasive procedure in which a solid filament needle is inserted into the skin and muscle directly at a myofascial TrP".

Sportscare Physical Therapy<sup>(54)</sup> states that "IMT is an invasive procedure in which a solid filament needle is inserted into the skin and muscle directly at a myofascial trigger point. A myofascial TrP consists of multiple contraction knots, which are related to the production and maintenance of the pain cycle."

#### **Expertise**

A medical dictionary<sup>(55)</sup> defines "manual therapy" as "(a) collection of techniques in which hand movements are skillfully applied to mobilize joints and soft tissues." (Medical Dictionary, © 2009 Farlex and Partners)

Ferguson,<sup>(55)</sup> Attorney General of Washington State, states that "DN is not 'manual therapy' as we understand the term".

The National Center for Acupuncture Safety and Integrity (NCASI)<sup>(56)</sup> states that "physical therapists contend that their right to practice DN arises by virtue of their right to practice manual therapy. The term manual therapy simply means a remedial treatment consisting of manipulating a part or the whole of the body by hand. It certainly does not include the practice of surgery (severing or penetrating tissues) in any form. Dry needling is acupuncture, not manual therapy".

In regulations of veterinary medicine, acupuncture procedure is often classified as a type of surgical procedures.<sup>(57)</sup> "Surgery" is defined by the American Medical Association (AMA), in part, as "the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles."<sup>(58)</sup> The insertion of acupuncture needles falls well within what is medically considered to be "surgery" by the AMA.

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) states that "DN is taught in American acupuncture schools as a form of treatment for individuals using acupuncture needles. DN is an invasive procedure. Needle length can range up to 4 inches in order to reach the affected muscles. The patient can develop painful bruises after the procedure and adverse sequelae may include hematoma, pneumothorax, nerve injury, vascular

injury and infection".<sup>(59)</sup>

AMA policy on DN states that "DN is indistinguishable from acupuncture", physical therapists and other non-physicians practicing DN should—at a minimum—have standards that are similar to the ones for training, certification and continuing education that exist for acupuncture. It emphasizes that "Lax regulation and nonexistent standards surround this (DN) invasive practice. For patients' safety, practitioners should meet standards required for licensed acupuncturists and physicians".<sup>(60)</sup>

#### Other Facts

Zhou, et al<sup>(8)</sup> reviewed DN history and compared the theories and techniques of DN and acupuncture and concluded that DN is a kind of Western acupuncture for treating myofascial pain. DN as a subcategory of acupuncture uses the same needles, similar stimulating points, the same or similar needling techniques, and involves the same biologic mechanisms.

Peng, et al<sup>(9,10)</sup> compared four aspects of DN with acupuncture: the points of the needle insertion, needles, needling techniques, and therapeutic indications. They concluded that DN can be called TrP acupuncture. It is an integral part of the traditional acupuncture.

Zhu and Most<sup>(11)</sup> reviewed four features of needling techniques and explored the similarities and differences between DN and acupuncture. The authors concluded that DN is one type of acupuncture when solid filiform needles are used.

#### AAPAS Comments

DN is a subset of acupuncture, also called TrP acupuncture. As the term indicates, it involves the procedure of piecing skin and other tissues of the body with different sized needles and is an invasive therapy instead of a manual therapy.

For patients' safety, practitioners should meet the standards required for licensed acupuncturists and physicians, as American Medical Association, et al have indicated.

#### Conflict of Interest

None.

#### Author Contributions

All authors participated in the planning, writing and proofread, and contributed equally and served as co-first authors.

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# A History of Dry Needling

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## ABSTRACT

**Objectives:** To trace the development of the practice and theoretical basis of dry needling by means of an examination of the literature.

**Findings:** The term dry needling arose from the need to provide a contrast to the injection of a fluid through a hypodermic syringe [now sometimes referred to as wet needling]. Dry needling does not involve the injection of any substance, merely the insertion of a needle. The history of dry needling is inextricably bound up with the search for effective treatment of painful musculoskeletal disorders. In particular, it was the research into the use of injections, to both cause and relieve pain in muscular tissue, that led to the development of trigger point theory and then to the use of dry needling as a treatment.

**Conclusions:** A search of the literature reveals that the important clinical finding that simple dry needling of tender points could produce profound and long-lasting relief of musculoskeletal pain had been published in 1941 and again in 1947. This provoked little interest in the wider academic or clinical community until the focus on acupuncture in the 1970s and the publication of a scientific explanation of the nature of myofascial trigger points in the 1970s and 1980s. Since 2000, there has been a surge in academic interest in dry needling and its use has expanded into the allied health professions of physiotherapy, osteopathy, and chiropractic.

**KEYWORDS:** Dry needling, history, musculoskeletal pain, myofascial trigger points

## INTRODUCTION

Dry needling involves the insertion of needles into tender points in the body without the injection of any substance. It is used to treat painful musculoskeletal disorders. The more common approaches, which are best supported by research, target myofascial trigger points (1).

Although the history of trigger point theory has been detailed in several publications (2,3), no description of the development of dry needling was found in the literature. In order to provide a historical context for this emerging modality, a search of the literature was undertaken.

The major texts of trigger point theory and dry needling were consulted. The Pubmed, Embase, and Physical Therapy and Sports Medicine databases were searched using the search terms trigger point, myofascial trigger point, tender point, and dry needling. Items retrieved were sorted for relevance

and duplication. The reference lists of the texts and the key papers were also mined for additional references.

Papers were retrieved if they offered the possibility of an initial or early reference to a key concept, finding, or technique, or if they could provide a statement of contemporary knowledge.

## EARLY TENDER POINT/TRIGGER POINT THEORY

Dry needling and trigger point theory emerged from the use of injections of anesthetic to treat painful musculoskeletal conditions. Before examining the early development of dry needling, it is worth exploring the early research that led to trigger point theory.

While the presence of tight bands and tender nodules in muscles has long been recognized in many cultures, their significance in the production

of pain was not really articulated in the West until the twentieth century. In the late nineteenth and early twentieth centuries, a multitude of terms was used to describe pain arising from the muscles, which reflected the lack of coherent understanding. These included muscular rheumatism, fibrositis, rheumatic myalgia, non-articular rheumatism, and fibromyositis (3).

The credit for getting on the right track is usually given to John Kellgren (2,4,6). In the late 1930s, Kellgren was working in University College Hospital in London under the supervision of Sir Thomas Lewis. Lewis had experimentally determined that injecting a saline solution into muscular tissue could lead to pain being experienced some distance from the site of the injection.

Lewis encouraged Kellgren to explore this phenomenon and both researchers published their findings in consecutive articles in the *British Medical Journal* in February 1938 (7,8). Kellgren's paper contained several important observations that have been substantiated by subsequent research:

- Pain from muscles is often referred. The pattern is specific to the muscle.
- Tenderness could also be referred.
- Tenderness was not a useful diagnostic guide unless the patient winced when a tender point was palpated [now known as the jump sign or recognition of pain by patient].
- Some pain could be relieved by injecting procaine into acutely tender points which were often at some distance from the site of the pain.
- The relief obtained often far outlasted the effects of the anesthetic and in many cases could be considered permanent.

Kellgren was also the first to publish detailed illustrations of the pain referral patterns from specific muscles (9).

Another researcher in the United Kingdom, who variously called himself Gutstein, Gutstein-Good, and finally Good, was also heading in the same direction, also publishing detailed illustrations of the referral patterns of different muscles and beginning, like Kellgren, in 1938 (2).

While it is hard to determine the effects of Good's work, there is little doubt that Kellgren's paper stimulated a flurry of interest over the next few years in the United States, the United Kingdom, Europe, and Australia. Exploring the use of anesthetic injection into tender points produced several important findings.

Harman and Young (10) published a case series in the *Lancet*, reporting that tender points in thoracic musculature could simulate visceral pain which could be eliminated by injecting the points.

Working in the United States, Arthur Steindler (11) was perhaps the first to use the term "trigger points". He reported that many cases of sciatica seem to involve referral from musculo/tendinous/ligamentous structures rather than from irritation of the sciatic nerve. His use of the term "trigger point" was not confined to myofascial trigger points.

In Australia, Michael Kelly was stimulated by Kellgren's paper to try the anesthetic injection technique for treating somatic pain. He was enthusiastic about the results and found the injection technique suitable for use in general practice. He wrote a series of papers on the subject between 1941 and 1962, beginning with a letter to the *British Medical Journal* in 1941 (5).

In 1942, Janet Travell and colleagues (12) published the first paper in what would turn out to be a lifelong contribution to the subject. Their use of the term "trigger points" was restricted to tender points in muscles. Travell's name and that of her longtime collaborator, Dr David Simons, became the most closely associated with the concept of myofascial trigger points.

Several of these early researchers (5,6) noted the difficulty of finding the most relevant tender points and remarked that this contributed to inconsistent clinical results.

The earliest paper identified in which the term trigger point occurred either as an index term, keyword, or in the title of a paper was by Pugh and Christie (13). It reported that trigger points were more common in servicemen with a history of musculoskeletal pain [more than 30%] than in those without such a history [3%].

A myofascial trigger point is defined as a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is tender when pressed and can give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena (4).

### **THE EMERGENCE OF DRY NEEDLING**

Dry needling did not emerge with any fanfare. It seems to have been an almost incidental development, arising out of the use of injection therapy to treat musculoskeletal pain. Its acceptance was perhaps bolstered a little by an awareness of the reported effects of acupuncture-type needling.

An important paper by Brav and Sigmond published in the United States in 1941 (14) made the claim that pain could be relieved by simple needling without the injection of any substance. It was a notable paper for several reasons. It was the

first paper found in the literature search that referred to this finding, which is central to the use of dry needling. Brav and Sigmond did not claim the observation as their own, however. The first line of the paper reads: “The origin of the local and regional injection treatment of low back pain and sciatica dates back to the earliest descriptions of acupuncture”. It goes on to reference Churchill’s publications on acupuncture which were published in 1821 and 1828.

The paper is a report of a clinical trial set up to explore several questions, principally the efficacy of anesthetic injection and the importance of the location of the injection. Sixty-two patients presenting with low back pain or sciatica and without underlying visceral disease were divided into three treatment groups. Each group received needling into the lumbar paraspinal musculature, close to but not into, the emerging spinal nerve. One group was injected with one percent novocaine, another with normal saline solution, and a third received the insertion of the hypodermic with no substance injected. The novocaine group received the best outcome and the “dry needling” [although it was not named as such] came in a close second which was described as a “startling” result.

Brav and Sigmond’s paper probably deserves wider recognition for its early and substantial findings. Only one paper was found which referenced it (15). That paper was, in turn, referenced by just one other (16) as the first mention of the finding that needling without injection could be effective.

The earliest mention of the term “dry needling” was by Paulett in the *Lancet* in 1947 (17). This paper reported on an investigation of 25 cases of low back pain with no evidence of organic disease. It is a revealing look at the nature of experimental investigation of the time with several lines of enquiry being enthusiastically pursued.

The part of the paper relevant to this discussion refers to attempts to eliminate pain by injection into the tender points. Paulett established that relief could be obtained not only from the injection of procaine but also by injecting saline and “even dry needling”. The needling method was described in detail. A relationship was reported between effective treatment and deep needling into the tender points that resulted in a jab of pain and a reflex spasm [local twitch response?] of the muscle. Subcutaneous needling or deep needling that was painless did not lead to a beneficial outcome.

In the United States, Janet Travell and Seymour Rinzler published a landmark paper on myofascial trigger points (18). It reaffirmed that a trigger point

was able to cause referred pain, pain that mimicked visceral conditions and autonomic phenomena. It suggested that the intense afferent stimulus from a trigger point was responsible for these phenomena and contained a series of illustrations showing the referral patterns from 38 muscles which provided a basis for reliable diagnosis and location of trigger points in those muscles.

This paper also included the brief and unreferenced statement that dry needling could be an effective method of treating myofascial trigger points [the only references provided were to previous papers by the authors themselves]. Several other authors have referenced this article as the earliest use of the term (19,20). It is entirely possible that Travell and Rinzler were aware of the papers by Brav and/or Paulett and based their comment on the findings made in those papers. An article by Steinbrocker, the only author found to have referenced Brav and Sigmond’s findings, was referenced in Travell and Rinzler’s 1942 paper (12).

By the 1960s, the concept of trigger points was established in the medical literature if not common in general practice. Although dry needling had been suggested as a treatment, the usual treatment was still the injection of anesthetic into the tender points.

Despite the early interest, the 1960s and early 1970s produced almost no important new insights into trigger point theory or dry needling. Only 21 papers published between 1960 and 1975 were found that included a reference to musculoskeletal trigger points. Three of these were reports of iatrogenic pneumothorax from injecting trigger points. The rest were case reports or reviews. No trials were reported. Writing in the *Journal of the American Osteopathic Association*, Mennell (21) remarks on the slow acceptance of trigger points as a cause of muscular pain. No articles are found when dry needling is used as a search term and no mentions of dry needling were found in any papers from this period.

### **ACUPUNCTURE “ARRIVES” IN THE WEST**

In the 1970s, China began opening up to the world. There was a surge of interest in acupuncture, particularly its use for anesthesia and in the treatment of painful conditions. A search using acupuncture as a search term produced 18 papers published in 1971 [a record up to that point], 99 in 1972, and 213 in 1973.

While most of the published articles were speculative discussions about the possible benefits of acupuncture for the treatment of pain, some clinical

trials were undertaken (19,22–24). Two studies were of particular relevance to the development of dry needling.

The trial carried out by Ghia et al. (22) is the first to compare needling at traditional acupuncture points versus tender points [dry needling]. It concluded that, as both were effective, the location of the needling perhaps did not matter so much. The important factor was the intensity of the stimulus which was considered to be crucial in producing the analgesic effect. Melzack (24) attempted to compare the locations of acupuncture points and trigger points and claimed a high degree of correlation.

### **DRY NEEDLING AND ACUPUNCTURE DIVERGE**

Chan Gunn, a United States based physician with an interest in treating pain, became interested in acupuncture in 1974 (25). Over the next few years, he explored the prevalence of tender points in several conditions (26,27) and concluded that most cases of chronic musculoskeletal pain were complicated by additional signs of radiculopathy (28). He developed an approach to dry needling that combined features of acupuncture [type of needles and needle techniques] with neurological and tender point models that he called intramuscular stimulation.

In 1979, Karel Lewit of Czechoslovakia published what is widely recognized as a landmark paper in the development of dry needling (20). “The Needle Effect in the Relief of Myofascial Pain” reported his results when needling tender points without injection. The study was a case series and included only cases of chronic pain. Lewit made several important observations in this paper which have had an impact on the development of dry needling:

- The effect of the technique depended on the intensity of the tenderness at the point and the accuracy of the needling.
- He clearly did not confine himself to myofascial trigger points in the narrower sense. Tender points in scars, ligaments, and periosteal insertions were all included in his study.
- He used acupuncture needles as well as hypodermic type needles in his treatments and found that the acupuncture needles were safer and produced less bleeding and bruising.
- He described the relief of pain resulting from dry needling as “The needle effect”.

A year later, in 1980, Gunn published the results of the first clinical trial of dry needling of motor points [not trigger points] for the treatment of low back pain (29).

Both Lewit and Gunn were clearly influenced by acupuncture. Gunn was president of the American

Society of Acupuncture. Lewit freely admits to having borrowed the needles of acupuncture to perform his needling.

The poor separation between the concepts of dry needling and acupuncture in the 1970s and 1980s is evidenced by the fact that two randomized trials that included dry needling as one of the interventions do not appear when “dry needling” is used as a search term. First, MacDonald et al. (30) showed that superficial dry needling of trigger points was superior to placebo but he called the treatment acupuncture.

Second, Garvey et al. (31) showed that a session of dry needling produced a similar degree of short-term global improvement as did two other injection regimes and cooling spray plus acupressure.

In 1989, Gunn published a manual of his intramuscular stimulation system of dry needling. The book *Treating Myofascial Pain* (25) was the first manual of dry needling with a good description and illustration of techniques for specific conditions. Gunn’s unique take on dry needling treatment was that the treatment of the shortened muscles should be combined with the treatment of the relevant spinal segments because the local muscular condition had been precipitated by a radiculopathy or neuropathy at the spinal segmental level. A second edition, *Treatment of Chronic Pain* (28), was released in 1996.

Also in 1989, Peter Baldry, a United Kingdom-based physician with an interest in acupuncture, published *Acupuncture, Trigger Points and Musculoskeletal Pain* (32). This was a well-illustrated and well-referenced manual that was substantially about dry needling. Importantly, he made some attempt to reconcile trigger point theory with traditional Chinese acupuncture theory and he did not confine his use of dry needling to myofascial trigger points. A second edition, *Myofascial Pain and Fibromyalgia Syndromes* (2), was released in 2001. This contained a lot more about the science of pain and myofascial trigger points and a lot less acupuncture than the first edition.

The change of emphasis found in Peter Baldry’s updated text (2) was characteristic of way dry needling was used by the turn of the century. Even though the use of acupuncture needles had become the norm in dry needling, the theory and techniques that dry needling relied on were very different to those used in acupuncture practice (1). Dry needling had become much more closely associated with trigger point theory (33) and with the manual therapy professions rather than the acupuncture profession (1).

## TWENTY-FIRST CENTURY DEVELOPMENTS

Only moderate interest was shown in dry needling during the 1980s and 1990s. Less than 30 published papers that included some discussion of dry needling of tender points were found that were published between 1980 and 1999. The situation rapidly changed after 2000 with around 100 such papers written between 2000 and 2013.

The surge in interest in dry needling since 2000 was not just reflected in the academic literature. The increased interest has been worldwide (1,34) and involves the medical, physiotherapy, chiropractic, and osteopathic professions (33). Dry needling courses have become popular in Europe, North America, and Australia. They can also be found in Africa and the Middle East. There are several plausible reasons that, when taken together, can explain the rapid adoption of the modality. These include the following:

- The emergence of dry needling using acupuncture needles. While the use of hypodermic syringes tends to be highly regulated, the use of acupuncture needles is much less so. Physiotherapists, osteopaths, chiropractors and even massage therapists became free, in many jurisdictions all over the world, to add this therapy to their practices.
- The basics of dry needling can be taught quite quickly (33). Many current courses introduce the basic material via an on-line component followed by just 1 or 2 d of practical instruction.
- The publication of Travell and Simons' hefty *Trigger Point Manuals* in 1983 [Volume 1: The Upper Body] (3) and 1993 [Volume 2: The Lower Body] (35) provided a wealth of clinically useful material. Although they did not recommend dry needling as the main form of therapy, they did contain a guide to the diagnosis and location of myofascial trigger points.
- The publication of Gunn's (25,28) and Baldry's (2,32) manuals provided treatment and diagnostic instruction for dry needling treatment.
- The science supporting the importance of myofascial trigger points as a potent source of pain has been shown to be fairly robust (4,36). Researchers such as Simons, Gerwin, Shah, and Hong have gone a long way towards explaining the physiological and biochemical basis of trigger points. There is a growing evidence base supporting the use of dry needling for myofascial trigger points (1,34,37).
- The clinical experience of using dry needling can be very satisfying for both practitioner and patient. Although it can be a bit hit and miss, a successful dry needling treatment of a severe and chronic tender point can produce dramatic results.

Twenty-four randomized controlled trials were found that included dry needling as a treatment and

there have been several systemic reviews of the literature (38–44) that have included some sort of dry needling in their terms of reference. While the findings of these reviews have been generally supportive of the efficacy of dry needling for painful musculoskeletal conditions, the evidence remains far from conclusive.

Several styles of dry needling have been described and tend to be simply classified according to depth of insertion (1,16,33). Superficial dry needling involves insertion that does not reach the trigger point and is often just millimeters deep. Baldry's superficial technique is a good example (43).

Deep needling, in contrast, aims to penetrate the trigger point or tender point. It is generally agreed that, with deep needling, a local twitch response is desirable (17,44–46). This is usually accompanied by a characteristic sensation.

## UNRESOLVED ISSUES

Despite the increased attention, there is little consensus about the use of dry needling other than as treatment for painful musculoskeletal disorder through the needling of tender points.

Some researchers and practitioners restrict the use of dry needling to the deactivation of myofascial trigger points (34,37,47,48). There is no doubt that the science is more robust in support of this use. About 70% of the articles found with significant reference to dry needling were restricted to a discussion of dry needling as a treatment for myofascial trigger points. It is likely that this is a reflection of its clinical use.

Other practitioners support a broader scope of use for dry needling. The earlier practitioners of dry needling included the needling of tender points in tendons, ligaments, and scar tissue as suitable targets (8,11,14,20).

In the more recent literature, there is an increased interest in dry needling for tendon problems (40,49–51). Travell and Simons (4) recognized that the taut bands produced by active and latent trigger points placed extra strain on tendon insertions which resulted in an enthesopathy or an attachment trigger point. As these are considered secondary to the central trigger point, they should resolve if the central point is resolved (52). Direct needling of the enthesopathy is only mentioned briefly.

The lack of consensus about what Lewit (20) termed "the needle effect" is interesting. The authors that subscribe to the concept that the role of dry needling is to de-activate myofascial trigger points

tend to focus on its ability to affect the dysfunctional endplate and the taut bands that result (16,34,37). It is likely, however, that the “needle effect” has a broader application and, while some will choose to stay within the confines of the robust evidence base, others will continue to extend the scope of practice and include ligamentous, scar, fascia, and possibly articular tissues as suitable targets for dry needling practice.

### CONCLUSIONS

It is clear from this review that the modality of dry needling emerged from the exploration of the role of tender or trigger points as a cause of muscular pain. The earliest mentions of dry needling in the literature were made in the 1940s (14,17) by researchers who have been insufficiently recognized for their pioneering contribution.

The roots of dry needling, and the theory on which it is based, are quite distinct from the practice of acupuncture. However, without the interest in acupuncture in the mid-1970s and the introduction of acupuncture needles into contemporary practice, it is likely that dry needling would never have become an established modality.

Once established dry needling was taken up enthusiastically by doctors, physical therapists, and other manual therapists all over the world. While not the exclusive domain of any one discipline (1), dry needling is a “cheap, easy to learn, low risk, and minimally invasive” (33) form of therapy that can be combined well with other modalities.

### DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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## Exhibit B.1 Auricular (Ear) Acupuncture Research

Language for Auricular Acupuncture:

(c) All points and protocols for ear acupuncture including, but not limited to, auricular acupuncture, national acupuncture detoxification association protocol, battlefield acupuncture, and the Nogier system;

Ear acupuncture research and information:

All the research clearly states that auricular acupuncture is part of acupuncture – this is universally understood, not just in the state but in the world.

[https://acudetox.com/wordpress/wp-content/uploads/2014/07/Research\\_Summary\\_2013-2.pdf](https://acudetox.com/wordpress/wp-content/uploads/2014/07/Research_Summary_2013-2.pdf)  
(specific research on 5 NADA ear points)

<https://www.ncbi.nlm.nih.gov/pubmed/25029046>  
(auricular acu for stressed nurses)

<https://www.ncbi.nlm.nih.gov/pubmed/30813193>  
(auricular acu for insomnia)

<https://shifa.clinic/evidence.html>  
(auricular for PTSD)

<https://www.fosters.com/news/20190516/acupuncture-used-to-treat-addiction-and-other-ills>  
(article on treating w/ ear acu from Poulsbo WA)

<http://www.auriculo.biz/en/auriculotherapy/>  
(website on nogier system)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2206232/>  
(research article specific to history of auricular and nogier system)

<https://www.acupuncturetoday.com/mpacms/at/article.php?id=31917>  
(article on battlefield acu)

<https://www.militarytimes.com/news/your-military/2018/02/09/battlefield-acupuncture-yes-it-exists-and-the-military-is-using-it-to-fight-troops-pain/>  
(article on military use of BFA for pain instead of opioids)

<https://www.battlefieldacupuncture.net/who-can-practice-battlefield-acupuncture-bfa/>  
(shows who can take battlefield acu classes; says not to take the class if acupuncture is not within your scope of practice)

## Exhibit C.1-Contact & Non-Insertion tools

### Language

*use of contact needling and non-insertion tools that include but are not limited to teishin, enshin, zanshin.*

### Further Clarification:

*Stimulation of the acupuncture points, either through insertion of needles or contacting the skin with non-inserting tools is all a form of acupuncture. Non-inserting techniques still provide the benefit of acupuncture and may be more appropriate for children or other sensitive individuals.*

### References

- Shonishin Acupuncture for Children by Brenda Loew

This article mentions the different techniques of stroking, tapping, etc. without mentioning the specific tools (enshin, teishin, zanshin)...Such tools are listed in the Classics and have been used for hundreds of years. Deep nervous system stimulatory needling is a modern (post Communist China) phenomenon.  
<https://www.acufinder.com/Acupuncture+Information/Detail/Shonishin+Acupuncture+for+Children>

- Japanese Acupuncture: A Clinical Guide by Stephen Birch

This book explains the history of needles in Japan (many more than just filiform, including teishin, enshin & zanshin).  
[https://www.goodreads.com/book/show/1603601.Japanese\\_Acupuncture?ac=1&from\\_search=true](https://www.goodreads.com/book/show/1603601.Japanese_Acupuncture?ac=1&from_search=true)

- Understanding Acupuncture by Stephen Birch

Also has a section on history of different needles.

This book clearly and vividly reviews the development of the theories and practice of acupuncture.

Readers will find a wealth of incisive historical research and realistic contemporary evidence. The book also explores the conditions and symptoms that indicate acupuncture as a possible treatment, and broadly describes the processes of diagnosis and treatment.

<https://www.us.elsevierhealth.com/understanding-acupuncture-9780443061790.html#panel1>

- Page 91 of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) Clean Needle Technique Manual 7th Edition. CCAOM is the accreditation body for acupuncture colleges and Clean Needle Technique is required. (PDF page is attached)

- New Mexico Scope of Practice

16.2.2.8 SCOPE OF PRACTICE: [ ]

E. the stimulation of points, areas of the body or substances in the body using qi, needles, heat, cold, color, light, infrared and ultraviolet, lasers, sound, vibration, pressure, magnetism, electricity, electromagnetic energy, bleeding, suction, or other devices or means;

[http://www.rld.state.nm.us/uploads/files/Acupuncture%20Rules%20-%20Book%20format%20-%20Rev\\_03\\_02\\_2015.pdf](http://www.rld.state.nm.us/uploads/files/Acupuncture%20Rules%20-%20Book%20format%20-%20Rev_03_02_2015.pdf)

### California Scope of Practice

§ 4937. Use of techniques and modalities afforded by licensure; Definitions

An acupuncturist's license authorizes the holder thereof: [ ]

(a) To engage in the practice of acupuncture.

(b) To perform or prescribe the use of Asian massage, acupressure, breathing

techniques, exercise, heat, cold, magnets, nutrition, diet, herbs, plant, animal, and mineral products, and dietary supplements to promote, maintain, and restore health. Nothing in this section prohibits any person who does not possess an acupuncturist's license or another license as a healing arts practitioner from performing, or prescribing the use of any modality listed in this subdivision.

(c) For purposes of this section, a "magnet" means a mineral or metal that produces a magnetic field without the application of an electric current.

[https://www.acupuncture.ca.gov/pubs\\_forms/laws\\_regs/laws\\_and\\_regs.pdf](https://www.acupuncture.ca.gov/pubs_forms/laws_regs/laws_and_regs.pdf)

7<sup>th</sup> Edition Manual Clean Needle Technique: English PDF Version excerpt;  
<https://www.coursehero.com/file/31543690/7thEditionManualEnglishPDFVersionpdf/>

## **11. Other Acupuncture-Related Tools**

### **Manaka/Japanese Acupuncture Tools**

#### *A Review of the Literature*

There is no evidence in the English language medical databases that there are any AEs associated with either Manaka pumping chords or Manaka hammer treatments.

#### *Preventing Adverse Events*

There are no common AEs associated with the use of Manaka products. General clean techniques and vigilance to avoid use of the Manaka pumping chords or Manaka hammer where there is an active skin infection or trauma should be sufficient to maintain the safety record of these treatments.

### **Shonishin Pediatric Japanese Acupuncture Tools**

#### *A Review of the Literature*

There is no evidence in the English language medical databases that there are any AEs associated with Shonishin treatments.

#### *Preventing Common Adverse Events*

There are no common AEs associated with the use of Shonishin products. General clean techniques, proper disinfection of such devices as noncritical devices, and vigilance to avoid use of the any reusable medical device where there is an active skin infection or trauma should be sufficient to maintain the safety record of these treatments.

## **William E. Fassett, PhD, RPh, FAPhA**

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2403 W. Carolina Ct. • Spokane, WA 99208-8690  
509.468.4900 • 509.413.1219 (Fax) • b.fassett@comcast.net

May 17, 2018

Susan Shultz, DC, EAMP  
4916 N.E. St. Johns Rd.  
Vancouver, WA 98661

Via e-mail (DrShultz@cascadiahealthcare.com)

Dear Dr. Shultz:

I am pleased to respond to your request for my thinking about whether pharmacists or wholesalers in the State of Washington may legally supply procaine, lidocaine, or other local anesthetics to East Asian medicine practitioners for their use in point injection therapy.

Point injection therapy is defined in statute in RCW 18.06.010(j) as follows: “(j) Point injection therapy (aquapuncture), *as defined in rule by the department*. Point injection therapy *includes* injection of substances, limited to saline, sterile water, herbs, minerals, vitamins in liquid form, and homeopathic and nutritional substances, *consistent with the practice of East Asian medicine*. Point injection therapy does not include injection of controlled substances in Schedules I through V of the uniform controlled substances act, chapter 69.50 RCW, or steroids as defined in RCW 69.41.300; ....” [*Emphasis added*]

The department has by regulation defined point injection therapy to include “subcutaneous, intramuscular, and intradermal injection of substances consistent with the practice of East Asian medicine to stimulate acupuncture points, AHSHI points, trigger points and meridians.” (WAC 246-803-030(10)(a)) The regulation lists, with greater precision, substances that may be used that were included in the statutory definition. The department further implicitly authorizes practitioners using point injection therapy to administer a drug not included in the statute – epinephrine; the department requires practitioners to be trained in its use in case of anaphylaxis (see WAC 246-803-040(5)). While the department cites RCW 70.54.440(4) for the standards for epinephrine training, it does not cite that statute for the authority for practitioners to administer epinephrine.

It does seem to me that the department has authority under RCW 18.06.010(j) to define by regulation additional substances – beyond those suggested in the statute – that may be used in East Asian medicine as long as they are consistent with East Asian medicine practice, and that the department has done so.

NPI: 1548258114

The department's current list of medications does not, in my view, include local anesthetics such as procaine or lidocaine. From a pharmacist's perspective, the recognized standard classification scheme for drugs and biologicals in the US is the AHFS Pharmacologic-Therapeutic Classification, which is incorporated in the International Classification of Diseases (ICD) and is used by state Medicaid programs and Health Canada. Procaine, lidocaine, and similar agents are separately classified in AHFS category number 72 – Local Anesthetics. (Lidocaine (administered IV) is also classified as an antiarrhythmic agent.) Procaine and lidocaine are synthetic local anesthetics; procaine is an aminoester and lidocaine is an aminoamide; neither can be characterized as a fat, carbohydrate, or protein, which are the recognized categories of nutritional agents. Therefore, a pharmacist or wholesaler could not reasonably distribute injectable local anesthetics to East Asian medicine practitioners based on the listing in the WAC.

Although they are not in the department's list, these agents are clearly widely recognized as agents used in point injection therapy and in trigger point injection therapy, both in East Asian medicine and in allopathic medicine. I won't repeat multiple citations supporting this conclusion – I assume your group is providing such material to the department. Patients seeking the relief provided by trigger point injections or point injection therapy will have reduced options when seeking care from East Asian medicine practitioners than when seeking care from certain other providers.

Other licensed health professionals in Washington that may administer local anesthetics by injection include physicians, nurse practitioners, physician's assistants, dentists, nurses, pharmacists and dental hygienists; physical therapists may administer local anesthetics via iontophoresis, which results in measurable levels of the drug at 5 mm or more below the surface of the skin.

Two western states recognize local anesthetics as agents for use in point injection therapy. Colorado specifically lists lidocaine and procaine in 4 CCR 738-1, rule 10, effective 5/30/16; New Mexico's expanded practice formulary includes procaine in NMAC 16.2.20.8.F (2)(b)).

My recommendation to your group is to seek the addition of "local anesthetics specifically manufactured for injection by means of hypodermic needles" to WAC 246-803-030 (10)(a). This will provide patients of East Asian medical practitioners access to the same agents as used by other practitioners (physicians, nurse practitioners, physician assistants) who perform trigger point or point injection therapy.

Sincerely yours,

William E. Fassett, PhD, RPh, FAPhA  
Professor Emeritus of Pharmacy Law & Ethics  
Washington State University

Andrew Schlabach EAMP

3712 NE 40th Avenue  
Vancouver WA 98661  
360.695.9591  
andrew@alloneplanet.com

June 19, 2018

Susan Shultz  
Cascadia Health Care  
Vancouver WA

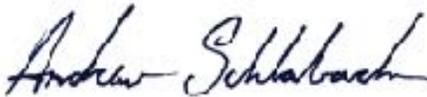
Dear Sue,

After receiving over 60 hours of continuing education and becoming certified to begin practicing Point Injection Therapy, I have run into several limitations in our approved scope of practice. I have received several referrals from Medical Doctors requesting this therapy as an alternative to surgery or at least an attempt to avoid surgical intervention. The problem I have in meeting the requirements of these referrals stems from our inability to utilize current, researched methods of orthopedic injections. Restrictions prohibiting the use of local anesthetics such as Procaine or Lidocaine diminishes our effectiveness in delivering satisfactory patient outcomes that are up to current industry standards of care.

The use and effectiveness of local anesthetics in Point Injection Therapy is well documented. Injectable gasses such as ozone are also widely accepted as a safe and effective Point Injection substance. These substances add to patient comfort and can dramatically improve therapeutic results.

Please allow this letter to serve as my petition to our governing body that the addition of local anesthetics and injectable gasses should be added to our scope of practice.

Sincerely yours,



Andrew Schlabach EAMP

### D.3 - PIT - Dr. Richardson



WA DOH & EAM Advisory Board:

My name is Scott Richardson, I am a Doctor of Acupuncture and Oriental Medicine. I have 4 year of Graduate level training and 2 years of Post Graduate training. In addition to my Masters and Doctorate degrees, I have also studied at Cheng Du University in China and did an apprenticeship in Taipei Taiwan. I am also a NCCAOM credentialed Continuing Education Provider for acupuncturists learning Point Injection Therapy.

For the last 6 years I have worked with the Colorado legislation, medical board and pharmacy board developing language regarding the safe practice of Point Injection Therapy and establishing a list of approved substances that protect the public while providing safe treatments for chronic pain and other conditions.

Local anesthetics are commonly used in Point Injection therapy and I would highly recommend including them as a permissible substances. This is consistent with best practices and they are non-narcotic and non-habit forming. Only a small amount is used and this helps the patient tolerate the treatment. Common local anesthetics are Lidocaine, Marcaine, and Procaine. There is a long established history of safe use with each substance.

I would also recommend specifying each substance or category of substances used in Point Injection Therapy. We are in our third revision of permissible substance list due to the language surrounding the substances used. While formulating a concise list may seem tedious, it establishes clear boundaries of what can be used. As a provider and teacher of Point Injection Therapy I would ask that you consider the following list:

Local Anesthetics Lidocaine, Marcaine, and Procaine, Dextrose, Glucose, and Maltose, Enzymes, Amino Acids, Vitamins, Minerals, Sterile Herbs, Saline, Hyaluronic Acid, Glucosamine, Sodium Chloride, Sodium Bicarbonate, Ozone and Homeopathic Substances. The use of topical Lidocaine should also be permissible and the use of epinephrine and oxygen should be allowed for patient care and safety. In accordance with best practices, the use of ultrasound guidance should be permitted to locate anatomical locations and landmarks. Again this protects the patients and increases treatment efficacy.

This list is consistent with other states that are establishing a list of permissible substances and is consistent with the training and testing received by acupuncturists.

If you have any additional questions or concerns regarding Point Injection Therapy, please do not hesitate to reach out.

Dr. Scott Richardson DAOM  
Doctor of Acupuncture & Oriental Medicine

**D.4 - PIT - Dr. Taylor**

May 6, 2018

Susan Shultz, DC, EAMP  
4916 NE St. Johns Rd  
Vancouver, WA. 98661

Re: Use of Procaine in Point Injection Therapy

Dear Dr. Shultz

In reference to our conversation, I would like to submit my opinion on the importance of Procaine in Acupoint Injection Therapy.

I have been practicing as a Doctor of Traditional Chinese Medicine since 1999 in Port Moody, British Columbia. I am also the Education Director of ARIABC (Acupoint and Regenerative Injection Society of British Columbia) I have 18 years of private practice experience in Acupoint injection and have been teaching courses in Acupoint and Trigger Point Injection since 2003.

When you asked me to present continuing education classes, I reviewed the list of substances allowed for injection in WA State. I was surprised that procaine was not included on the list. It is an essential component in the majority of solutions used in Acupoint Injection techniques.

Procaine is a fundamental element in the treatment of trigger points (also called acupuncture ah she points). Janet Travell, MD in her 1983 book discussed research using saline alone or saline with procaine. The latter was much more effective at treating trigger points with the concentration of 0.5%.

Procaine is the analgesic of choice because it is easily metabolized, improves microcirculation, benefits edema and inflammation and reduces pain of intramuscular injection.

The 24 hours of continuing education required before performing acupoint injection is ample time to cover safety aspects in the use of procaine.

As I review your state law, it is unclear if the use of ozone is allowed in WA State. I wonder if it is considered a 'nutritional substance' and therefore allowed. You could ask the WA DOH for clarification, because the use of ozone is also an essential part of Acupoint Injection Therapy.

If you have any further questions, please contact me at my office

Sincerely



Andrew Taylor, D.TCM



# FAMILY HEALING CENTER

NATURAL HEALING AND WELLNESS

CHRISTINA CAPTAIN, DAOM, MSAOM, MSHN, MA, AP

To: Dr. Susan Shultz, DC, EAMP  
4916 NE St. Johns Rd.  
Vancouver, WA 98661

From: Dr. Christina Captain, DAOM, MSHN, MA, Dipl. Ac, AP  
2650 Bahia Vista St Suite 101  
Sarasota, FL. 34239

Re: Point Injection Therapy Washington State

Dear Dr. Shultz,

Thank you for asking me to author a letter regarding, the use of local anesthetics specifically Procaine and Lidocaine in Point Injection Therapy (PIT). As you know I have been a licensed Acupuncturist since 2000, PIT certified (2005) and began certifying other licensed acupuncturists for PIT in 2010.

About your question of the use of local anesthetics in Point Injection Therapy (PIT) I offer the following response. The use of local anesthetics is and has been an integral part of modern PIT and serves to greatly benefit patients seeking relief from acute and chronic pain as well as other ailments, such as insomnia and depression, especially in combination with Eastern Medical/Acupuncture theory.

In fact, I would argue that Procaine HCL is a combination of nutrients and metabolizes (breaks down) in the body as a nutrient. Procaine HCL is a combination of P-aminobenzoic acid which is PABA, part of the folic acid molecule and dimethylaminoethanol (DMAE) which is a precursor to the B family nutrient, choline and naturally produced in the human brain. By virtue of this definition Procaine HCL would be an allowable substance under the nutrient category. However, it is also a local anesthetic similar to Lidocaine and because of this action is sometimes questioned as an allowable substance for use in PIT.

Procaine and Lidocaine are not controlled and not listed anywhere in schedules I through V of the controlled substance list published by the FDA. The current WA law as written creates confusion regarding the legal use of local anesthetics. In my opinion the 24 hours required for training before providing PIT in WA State is ample time to discuss contraindications and precautions necessary for the safe use of local anesthetics.

I would strongly encourage the addition of "use of local anesthetics" be added to the law. This would benefit patients as the use of non-controlled substances such as Procaine and Lidocaine would be highly productive in the resolution of pain and many other health issues and benefit licensees to practice within the specific confines of the law as written.

Thank you for consideration of my opinions in the resolution of this issue.

Respectfully,

Dr. Christina Captain, DAOM



Susan Shultz, DC, EAMP

December 1, 2018

4916 NE St Johns Road

Vancouver, WA 98661

Re: WAC 246-803-030

Dear Dr Shultz, After reviewing the WAC 246-803-030 it appears there would be very few items I as a Pharmaceutical Distributor could provide for you. . The list of items under the current WAC would limit me to providing Saline and Sterile Water for injection. The wording of the WAC is to broad in term (Minerals and Vitamins in liquid form) to be certain what FDA approved mass produced items would qualify. If there are some specific items you would use, perhaps including them as a guide to your intentions.

You may want to discuss following the lead of other healthcare specialist if you are going to consider injectables like Lidocaine, Procaine, etc. Consider terminology like " Local Anesthetic " for those items and then in parenthesis (like Lidocaine, Procaine, Marcaine).

I hope this is helpful. Please feel free to follow up with me if you have any other questions.

Respectfully,

A handwritten signature in black ink, appearing to read "Tim Dempsev", written over a horizontal line.

Tim Dempsev, Operations Manager

E.2 - PIT - Common Substances Utilized

**COMMON SUBSTANCES UTILIZED IN POINT INJECTION THERAPY and TRAINING REQUIREMENTS as LISTED BY STATES**

<b>State</b>	<b>Substances Specified within the Scope of Practice</b>	<b>Specific Training Requirements</b>
Colorado	<p>All vitamins, minerals, homeopathics, and herbals specifically manufactured for non-intravenous injection, such as:</p> <ul style="list-style-type: none"> <li>Saline</li> <li>Dextrose</li> <li>Enzymes except urokinase</li> <li>d-Glucose</li> <li>Glucose</li> <li>Homeopathic substances</li> <li>Hyaluronic acid</li> <li>Lidocaine</li> <li>Procaine</li> <li>Marcaine</li> <li>Oriental herbs</li> <li>Vitamin B-12</li> <li>Traumeel</li> <li>Sarapin</li> <li>Sodium chloride</li> <li>Sterile water</li> <li>Vitamins</li> <li>Cyanocobalamin, B12</li> <li>Epinephrine</li> <li>Oxygen</li> </ul>	<p>No hours specified.</p> <p>Acupuncturists employing injection therapy shall use only those substances and techniques for which they have received training. Required educational coursework shall include: Anatomy and Physiology, acupuncture physical exam and differential diagnosis, acupuncture point location, including underlying anatomy, acupuncture needling technique, general injection safety, acupuncture point injection therapy, pharmacology and clean needle technique certificate through NCCAOM</p> <p>Instruction on the used of inhaled O2 and IM epinephrine for emergency use is required</p>
Florida	<p>Herbs Homeopathics Nutritional Supplements</p> <p>“Acupoint Injection Therapy” – injection of herbs, homeopathies, and other nutritional supplements in the form of sterile substances into acupuncture points by means of hypodermic needles to promote, maintain, and restore health for pain management and palliative care; for acupuncture anesthesia; and to prevent disease.</p>	<p>60 hours</p> <p>Private for profit PDA/CEU providers in Florida have developed a “certificate program” for this requirement.</p>

New Mexico	<p><b>Basic Injection Therapy</b> includes:  Homeopathic medicines  Dextrose  Enzymes (except urokinase)  Hyaluronic acid  Minerals  Sarapin  Sodium chloride  Sterile water  Vitamins</p> <p><b>Expanded Injection Therapy (Rx-1, Rx-2)</b>  includes all substances from basic injection plus:  alcohol, amino acids, autologous blood and blood products and appropriate anticoagulant, live cell products, ozone, bee venom, beta glucans, caffeine collagenase, dextrose, dimethyl sulfoxide, gammaglobulin, glucose, glucosamine, glycerin, hyaluronidase, methylsulfonylmethane, phenol, phosphatidylcholine, procaine, sodium hyaluronate, sodium morrhuate, therapeutic serum.</p>	<p>Certified as Expanded Rx-1: 60 additional hours of education in evaluation, differential diagnosis, orthopedic and neurological evaluation, pharmacology, compounding drugs, storage, record keeping, dispensing, pharmaceutical law, injection theory &amp; practice for Basic Injection, 4 hrs American Heart Association CPR or BLS;  or  Certified as Expanded Rx2: 95 additional hours of education in theory and practice of injection therapy, oxidative and ultraviolet medicine, detoxification therapy, hormone therapy, evaluation, diagnosis, pharmacology, compounding drugs, storage, record keeping, dispensing, and Oriental medicine scope of practice; includes 28 hours in injection theory &amp; practice for Basic Injection.</p>
South Carolina	<p>Any sterile medicinal liquid:  Herbal injectables  Western medicinal injections  Homeopathics  Nutritionals  Normal saline  Vitamins</p> <p>Any sterile medicinal liquid which can be used for intramuscular injection is suitable for acupuncture injection therapy. Commonly used sterile Herbal Injectables: Gan Cao (Glycyrrhizae), Dan Shen (Salvia), Ai Ye (Fo. Artemisiae Argyi), Western Medicinal Injections, Homeopathics, Nutritionals, Normal saline, Vitamins.</p>	60 hour course.
Washington	Saline, sterile water, herbs, minerals, vitamins in liquid form, homeopathics, nutritional substances, does not include controlled substances contained in Schedules I through V	24 hours with up to 2 hours of training in the use of intramuscular ephedrine.
Utah	Nutritional substances, local anesthetic, autologous blood, sterile water, dextrose, sodium bicarbonate, sterile saline	No hours listed. Clean needle technique certification from NCCAOM and if doing autologous blood practitioner must hold a current phlebotomy certification

## F.1 - Curriculum - Dr. Captain

Course Title: Acupuncture Point Injection Therapy for EAMP – 24 hour Certification Course

Instructor: Dr. Christina Captain, DAOM, Dipl. Ac., MSAOM, MSHN, MA, AP, SLP

### Curriculum

- Course Review
- Text Review - Forms
- WA laws and Rules
- Introduction to AIT Theory/Principles
- Pharmacology – RED FLAGS, pharmacodynamics, pharmacokinetics
- Differential Diagnosis
- AIT Anatomy
- Instruments & Techniques – Aseptic Technique
- Acupuncture Injection Procedures - contraindications -practice
- Allergy Testing
- Emergency Procedures – Universal precautions
- Pharmacology - Authorized substances WA
- Understanding nonscheduled (I-V) drugs, topical/local anesthetics uses, contraindications
- Vitamins/Minerals
- Demonstration - practice
- Questions- Review
- Physical Exam Review
- Review of TCM Diagnosis, Applied to AIT
- Differential Diagnosis
- Herbal Formula – PIT
- Homeopathic Substances & Protocols
- Hevert – case studies – Practice
- Questions- Review - Practice Management
- Insurance Billing – Documentation – record keeping
- Storage of Injectables - Suppliers/Vendors
- Malpractice Insurance
- Epinephrine Auto injector Training - practice

## F.2 - Dr. Captain Certification Course

**From:** Dr. Christina Captain, DAOM [dr\\_captain@familyhealingcenter.com](mailto:dr_captain@familyhealingcenter.com)  
**Subject:** Summer Point Injection Therapy Certification Course 2019 - Take your practice to the next level!  
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Point Injection Course - Washington State June 21-23

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## NATURAL HEALING AND WELLNESS

CHRISTINA CAPTAIN, DAOM, MSAOM, MSHN, MA, AP

### FHC Continuing Education

#### Point Injection Certification Course

Approvals: This course offers 24 (pda) hours NCCAOM  
Course meets the requirements for licensed (WA) acupuncturists to practice Point  
Injection Therapy (PIT).

**Dates:** June 21-23, 2019

**Course hours:** 24

**Course fee:** \$950.00

**Course description:** This 24 hour course will qualify the Washington  
licensed East Asian Medicine practitioner for injection therapy.

Participants will review physical exam,  
contraindications and  
universal precautions. Understand clinical



theory, differential diagnosis injection techniques and protocols for diseases and injuries appropriate for treatment with PIT. Homeopathic remedies, Vitamins/Nutrients & Herbals for injection will be reviewed and practiced. The use of intramuscular epinephrine will be presented.



This course is presented in **three 8 hour days**. Class hours are **8:00AM - 5:00PM**, with one hour lunch breaks.

**Course Location:** Bellevue, WA

605 114th Ave SE, Bellevue, WA 98004•(425) 637-8500

[marriott.com/bvuri](http://marriott.com/bvuri)

**Course Registration:** To register for this class please call 941-951-1119 or by replying to this email.

#### **NOTE: Cancellation Policy for Live Classes**

- 15% cancellation fee up to 30 days prior to class
- 50% cancellation fee up to 14 days prior to class
- no refunds thereafter

**About the Instructor :** Dr. Christina Captain, DAOM, MSAOM, MSHN, MA has been practicing Medicine since 2000 and incorporates nutritional strategies & injection therapy in the treatment of her patients. Utilizing laboratory testing as well as modern Asian Medicine techniques she has an integrated approach to practice. In addition to earning the post graduate specialty doctorate (DAOM) from AOMA graduate school of Integrative Medicine, she earned a Master of Science degree in Human Nutrition from the University of Bridgeport, CT. She is co-author of "Laboratory Analysis for the TCM Practitioner", which was published by Singing Dragon and available on Amazon. Christina is a nationally board certified (NCCAOM) acupuncture physician and the lead practitioner at the Family Healing Center. Prior to becoming a practitioner of Asian Medicine, Dr. Captain earned a Master's degree in

Speech Language Pathology and Communication Disorders from the University of Central Florida, Orlando, Florida. Christina's knowledge and enthusiasm for health and wellness has earned her a reputation as a qualified lecturer, keynote speaker, and experienced teacher throughout the United States. Dr. Captain meets and exceeds the requirements of the Washington Code for instructor of PIT.

## **TESTIMONIALS**

*"I am professional licensed acupuncturist; who is always seeking the highest standard of continuing education courses. Dr. Captain's courses are a worthy investment of my time, money and resources. This course exceeded my higher education goals expectations; My expectations were meant by the course being current, engaging, specialized, and safe. I plan on investing in future courses with Dr. Captain, and highly recommend acupuncturists to take her courses."*

*Karin T. Washington 2018*

*"Taking the AIT course with Christina has added value to my acupuncture practice that I could not have imagined! The state of Washington only recently incorporated acupuncture injection therapy into the LAc scope of practice in 2017 so Christina's AIT course was a fantastic opportunity to level up healing treatments for my patients. I had researched other AIT courses in WA and CO but decided on Christina's and came away very satisfied. She is a knowledgeable, supportive, and captivating educator. She made the material easy to comprehend, digest, and to effectively put to use immediately the next day in clinic! Patients and myself are continuously impressed with the difference AIT has made to obtaining accelerated and extended results. Thanks Christina!!!"*

*Joie 2018 – Washington*

*"Having taken more courses than I can even try to remember, I have to say that Christina Captain's Acupuncture Injection Therapy course stands out as one of the best. Spread out over three 20 hour weekends, the format of teaching was one that allowed for proper digestion of the vast amount of information offered. The fact that we were able to practice with B12 and actual homeopathic medicines elevated the whole experience. At*

*first, I was hesitant to take the class because of the way it was spread over the 3 weekends, but, having taken the course, I now understand why Dr. Captain structured the classes in this fashion. Honestly, it's so much information that the time between classes helped me digest it all properly. Dr. Captain is incredibly gifted as an instructor. She's fun and she takes the time to make sure that each and every student understands the material offered, and is able to inject properly. Did I mention that we were able to practice with ACTUAL B12 and homeopathic medicines because THAT was an amazing bonus! I happened to have been suffering from acute lower back pain on one of the weekends, so Christina used me as a "patient in front of class." Not only was I able to experience what the treatments felt like, I was able to see how effective (and quickly) the medicines actually worked. I HIGHLY recommend Dr. Captain's courses.*

**A+++**

*- Carlos Sessler, A.P., Gainesville, FL - 2017*

***"Acupoint Injection Therapy CE (continuing education) courses just completed!!!!!! Christina Captain, (DOM & AP) teaches these classes with panache. Her educational methodology incorporates effective communication, competent and knowledgeable information in a 60 hour course which is well organized and directed. Her guest speakers were of equal caliber. Her sense of humor and attention to detail are greatly appreciated as well as her compassion and going above and beyond the "standard" in teaching or treatment. I highly recommend her courses! Thank you Christina Captain for sharing your knowledge and expertise!"***

***Sharon Baird, DOM, AP - Ft Lauderdale, FL. June 2015***

***"Dr. Captain's Acupuncture Injection Therapy seminar was most thorough and professional. She has a wonderful delivery style and couldn't be more engaging. I learned so much more than expected and her guest speakers were extremely knowledgeable. I highly recommend this seminar and look forward to many more of her continuing education classes."***

***Teresa Renfroe, DOM, AP  
Tampa, Fl***

***"Thank you for the excellent and enjoyable Acupuncture Injection Therapy Certification Course. I especially appreciated your clear, detailed***

***but fun teaching style! The addition of guest speakers added different viewpoints and approaches to AIT that helped me see ways to specialize. It was the hours of demos and practice that really made me feel confident in being able to add AIT to my Chinese Medicine Tool Chest!***

***Thanks again and I look forward to more training with you.”***

***Joyce Lockwood, A.P., Dipl.Ac. - St.Pete Beach, FL - 2015***

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**Andrew Taylor of ARIN-Acupoint and Regeneration Injection Network**

<https://www.advancedhealingarts.ca/acupoint-injection>

Courses are 22.5 hours for the 3-day courses and 15 hours for the 2-day courses.

ARIN.INC INJECTION COURSES:

**Acupoint 1&2** covers fundamentals and Acupoint, Trigger Point and Perineural Techniques from the waist down.

**Acupoint #3** covers the waist up and Perineural for the neck.

**Acupoint #4** covers deep injections to the neck and head. (Must have been injecting for 2 years plus Prolo #1 to be eligible for Acupoint #4)

**Bonepecking & Prolotherapy Parts 1-3** cover the appendicular skeleton and axial skeleton.

**Prolo#1** covers the si joint and ligaments, elbows, knees, shoulders, ankles and hips.

**Prolo#2** covers the lumbar spine and more detail on the appendicular skeleton including ultrasound guided injection.

**Prolo#3** covers the cervical spine and skull using multiple approaches from prolo, trigger point, deep ozone injection and PRP (Platelet Rich Plasma). Complex deep injections are covered in Prolo#3. (Prolo#1&2 are prerequisites for Prolo#3)

**Phlebotomy**-This course is taught by Stenberg College. Please contact ARIABC prior to registering.

**Ultrasound Guided Injection**- (In the works) These courses will prepare the participant to sit the RMSK exam.

Must have minimum of 1900 hours of TCM/Acupuncture school training.

**3 levels of training each with 60 hours of training.**

**Acupoint injection Level 1** covers soft tissue like trigger points 60 hours including practical

**Bonepecking/Prolotherapy Level 2** Appendicular Skeleton 60 hours

**Bonepecking /Proltherapy Level 3** Axial Skeleton.60 hours



# California Institute of Integral Studies

December 6, 2018

To Whom It May Concern,

I am writing this letter in support of clarification of substances to administer acupoint injection therapy in the practice act for East Asian Medicine Practitioners in the state of Washington.

From 1999 to 2017, I provided testimony, research and served as a subject matter expert for the Colorado Department of Regulatory Agencies in the original adoption of the 1999 Director's policy finding that acupoint injection was in the scope of Colorado licensed acupuncturists to the adoption of the 2016 Injection Therapy rule authorized by the Colorado Acupuncture Practice Act.

In providing the subject matter expert opinion on the rule that was eventually adopted, I provided findings of a literature search for adverse events connected to acupoint injection. I could find no adverse events in the literature regarding substance injection of saline, sterile water, dextrose, glucose, homeopathic substances, hyaluronic acid, Sarapin, and vitamins with the exception of cyanocobalamin. I conducted a similar search and could not find adverse events on ozone injection therapy.

Injection of cyanocobalamin, or vitamin B12 is associated with rare reports of anaphylactic reaction. In addition to B12 injection, acupuncture practitioners in Colorado had been given the authority to use injectable Lidocaine and Procaine since 2004. When the current Rule 10 allowing use of B12 and Procaine and Lidocaine were adopted, there had been no single incident of injury due to injection therapy. Authority to use any form of injectable epinephrine and oxygen was added for practitioners who chose to employ B12 and Lidocaine or Procaine.

From 1999 to 2017, I worked at Southwest Acupuncture College in Boulder, CO as a full professor and lead administrator involving curriculum development. In that period, I was responsible for the development of the curriculum that led to the state required education for the New Mexico, where my college had a branch. In that capacity, I developed the educational curriculum for the use of B12, procaine, and the use of oxygen and epinephrine as part of a safety plan required of acupuncturists who used B12 and lidocaine/procaine. The proposed 24 hours of training are adequate to train LEAP to safely use the expanded list of substances and any emergency medications.

Please feel free to contact me if you have any questions or need further information.

Sincerely,

A handwritten signature in black ink that reads "Valerie Hobbs". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Dr. Valerie Hobbs, DAOM, Dipl. O.M (NCCAOM®)  
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## G.2 - Kris Justesen Letter

Alpine Wellness Center  
Kris Justesen, O.M.D., L.Ac.

1664 E Dawn Drive  
Cottonwood Heights, Utah 84121

Phone 801-263-9380  
E-mail [drj@alpinewellnesscenter.com](mailto:drj@alpinewellnesscenter.com)  
[www.alpinewellnesscenter.com](http://www.alpinewellnesscenter.com)

Dr Susan K. Shultz  
4916 NE St. Johns Rd Vancouver, WA. 98661

Dear Dr Shultz,

Thank you for the opportunity to review and provide feedback on the Washington State Acupuncture License Act, WAC 246-803-030, particularly the list of substances allowed for Point Injection Therapy. You asked me for my opinion on how to make the list more in alignment with current practices and 'State of the Art' point injection therapy (PIT) performed by L.Ac's. in other states across the country.

I have been practicing Acupuncture for 32 years, including Acupoint Injection for 23 years. I have taught Acupoint injection courses to L.Ac's from all over the United States including a 3 day 24 hour classes to practitioners from WA State. I teach a series of courses, including coordinating classes with an advanced Acupuncture and Point Injection practitioner from Canada, each class building on the previous class.

I would recommend that you add 'local anesthetics', and other substances that "may include" NCCAOM list of substances recognized on their website. Local anesthetics are widely used in both Acupoint Injection and Trigger Point Injection in Eastern and Western Medicine. Besides making the procedure less painful, procaine in particular is metabolized as PABA, a B vitamin locally on a cellular level, which acts as a nerve calming and resetting agent as well as providing benefits of reducing edema and inflammation. Although 'local anesthetics' are not schedule I through V substances, it would be more clear if the words 'local anesthetics' were added to the list.

Autologous Blood is already a long standing tradition in Traditional Eastern Acupuncture Medicine. Look at "cupping" which floods the area with the persons own blood (autologous-self blood). Techniques such as wet cupping, which includes puncturing or piercing the skin followed with a suction cup to draw small or larger amounts of blood out of the tissues for therapeutic benefits. Plum-Blossom or seven star needle techniques to render multiples of tiny punctures to draw blood out. Some are left or rubbed across the skin for the body to benefit from the persons stem cells and growth factors to be reabsorbed by the open punctures. Others that could be cited including separating plasma from red blood cells and injecting into acupuncture points for the benefits of plasma, growth factors and other substances for their therapeutics at the given Acupuncture points. Also, the use of human placenta in various forms as an integral part of our medicine for thousands of years.

Your scope includes the use of oxygen and epinephrine which I view as absolutely necessary for the benefit of the patient and for any safety issues. I would also recommend the use of Ultrasound guidance in accordance with best practices of Injection therapy, to ensure patient safety and location of anatomical structures.

Again, thank you for the opportunity to review and render an opinion of Washington State Acupuncture Point Injection Therapy.

Warmly,



Kris Justesen, OMD, LAc



11-20-2018

To Whom it may concern,

I have been practicing acupuncture for almost 30 years, APIT has always been an important treatment modality in my work, I have used it and taught it to other professionals. I am very grateful that it has been validated, recognized and regulated in the state of Washington. We have been granted access to many different substances for therapeutic purposes, most of which are included in the chinese pharmacopoeia. Of all of these substances a very important group that I believe should be included in our scope of practice is local anesthetics, since they are used worldwide by health professionals to enhance the effectiveness of point injection therapy.

In my professional opinion adding the group of local anesthetics to the list of substances allowed in point injection therapy would benefit the patients, practitioners and our profession as a whole by amplifying the therapeutic benefit of the modalities already in our scope of practice. It reduces the number of needles used in an acupuncture session, frequency of sessions, pain at the injection site and increases absorption of other substances used in the injections due to increased cell membrane permeability. Local anesthetics could be easily integrated into the required training for APIT, as is epinephrine.

Thank you for your consideration

Sincerely,

William B. Duarte, DAOM, LAc, EAMP



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**Borrower:** ORUGYK

**Lending String:**

**Patron:** Shultz, Dr. Susan

**Journal Title:** Quintessence international (Berlin, Germany : 1985)

**Volume:** 43 **Issue:** 8

**Month/Year:** 2012 **Pages:** 695-701

**Article Author:** Yan Z;Ding N;Hua H

**Article Title:** A systematic review of acupuncture or acupoint injection for

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# A systematic review of acupuncture or acupoint injection for management of burning mouth syndrome

Zhimin Yan, DDS, PhD<sup>1</sup>/Ning Ding, BDS<sup>2</sup>/Hong Hua, DDS, PhD<sup>3</sup>

**Objective:** Burning mouth syndrome (BMS) is a common chronic pain condition that lacks a satisfactory treatment approach. This systematic review was designed to examine the effects of acupuncture or acupoint injection on the management of BMS and to evaluate the evidence supporting the use of acupuncture therapy for BMS in clinical practice. **Method and Materials:** The following databases were searched for relevant articles: Cochrane Oral Health Group Trials Register (July 2011), Cochrane Central Register of Controlled Trials (issue 7, 2011), MEDLINE (1966 to June 2011), and electronic medical database from the China-National Knowledge Infrastructure (1979 to June 2011). Articles were screened, and the quality of the included trials was assessed independently by two reviewers. **Results:** After screening, nine studies with 547 randomized patients were included in this review. All nine articles were published in Chinese and were clinical trial studies with a Jadad score < 3. Their results showed that acupuncture/acupoint injection may benefit patients with BMS. The evidence supported the efficacy of acupuncture/acupoint injection therapy in reducing BMS pain and related symptoms. **Conclusion:** In light of the positive outcomes reported, the use of acupuncture therapy for BMS patients warrants further research. (*Quintessence Int* 2012;42:695-701)

**Key words:** acupoint, acupuncture, burning mouth syndrome, pain, therapy

Burning mouth syndrome (BMS) is a chronic pain condition characterized by pain or a burning sensation affecting the oral mucosa in the absence of visible abnormality. The International Association for the Study of Pain and International Headache Society define it as a distinctive nosological entity and a pain of at least 4 to 6 months duration on the tongue or other mucosal membranes in the absence of clinical or laboratory findings. In the general population, the prevalence of BMS ranges from 0.7% to 15% and is more common in women, particularly after menopause.<sup>1</sup> To date, the etiology of

BMS is poorly understood, and the disorder presents clinical and therapeutic challenges.<sup>2</sup> Although pharmacologic options such as antidepressants and analgesics remain the primary management strategy, many patients continue to experience distress and pain after such treatments.<sup>3</sup> Moreover, the adverse effects of medication may lead to the consideration of nonpharmacologic treatment.

Acupuncture is an alternative medicine involving the insertion and manipulation of fine needles in different parts of the body. It can be used for therapeutic purposes to relieve pain, treat diseases, and promote general health. The term *acupuncture* is also sometimes used to refer to water needling (acupoint injection) or to applying an electric current to needles in acupuncture points. All of these acupuncture therapies have been widely used to manage chronic pain conditions (eg, headache, fibromyalgia, and head and neck pain), and their efficacy in reducing pain intensity has been demonstrated in the literature.<sup>4-6</sup> For BMS, however, there is a lack of evidence regarding the use of acupuncture

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**Correspondence:** Dr Hong Hua, Department of Oral Medicine and Traditional Chinese Medicine, Peking University School of Stomatology, 22 South Zhongguancun Ave, Haidian District, Beijing 10081, China. Email: honghua68@hotmail.com

treatment. Therefore, this systematic review aimed to evaluate the evidence regarding the efficacy acupuncture treatment in the management of BMS.

## METHOD AND MATERIALS

### Search strategies

The following databases were searched for relevant articles: Cochrane Oral Health Group Trials Register (July 2011), Cochrane Central Register of Controlled Trials (issue 7, 2010), MEDLINE (1966 to June 2011), and electronic medical databases from the China National Knowledge Infrastructure (CNKI) (1979 to June 2011). All articles in the CNKI are in Chinese.

Key words used for searching included *acupuncture*, *acupoint*, *burning mouth syndrome*, and *glossalgia*. A total of 81 trials were found. Abstracts of these studies were screened by two independent reviewers (Z.Y. and N.D.). The full texts of the relevant articles were obtained for further review. Data from letters, abstracts, conference proceedings, case reports, reviews, or non-controlled studies were excluded.

### Selection criteria

Studies were selected if they met the following criteria: study design—randomized controlled trials and controlled trials; participants—patients with burning mouth syndrome, ie, oral mucosal pain with no dental or medical cause for such symptoms; interventions—acupuncture or acupoint injection evaluated in controlled trials; and primary outcome—relief of pain/burning.

Studies were included only if at least one clinical outcome related to burning sensation (eg, intensity, healthy-related quality of life) was evaluated and recorded. Trials of other acupuncture techniques, such as acupoint injection, were included. Trials using acupuncture points other than needling (eg, millimeter wave therapy) were excluded.

### Quality assessment

The quality of each included study was assessed by two independent reviewers based on the criteria of the Jadad Scale.<sup>7,8</sup> When any difference of opinion occurred

between the two reviewers, consensus was reached by discussion or consultation of a third party. Only articles that received a Jadad score  $\geq 1$  were included. The maximum score was 5 (2 points for descriptions of randomization, 2 points for descriptions of double blinding, and 1 point for descriptions of withdrawals). Points were awarded as follows:

- Was the study described as randomized? (yes, 1 point; no, 0 points)
- Was the randomization adequate? (yes, 1 point; no, 0 points)
- Was the study described as double blind? (yes, 1 point; no, 0 points)
- Was the blinding adequate? (yes, 1 point; no, 0 points)
- Was there a description of withdrawals and dropouts? (yes, 1 point; no, 0 points)

### Data extraction

Two independent reviewers extracted information on participants, intervention, and outcome measurements. The primary outcome was pain relief, and the secondary outcomes were changes in dry mouth, taste, and other somatic symptoms. The primary outcome measurement was needed for inclusion, while secondary outcomes were not necessary.

## RESULTS

### Study characteristics

The two reviewers identified 81 potentially relevant trials. After screening, nine trials consisting of 547 participants met the inclusion criteria and were included in this review (Fig 1). All nine trials were exclusively published in Chinese from 2002 to 2010. No trials published in English were found. The characteristics of the included trials are summarized in Table 1. Six articles reported that the burning sensation had a duration of more than 3 months. Eight trials used acupoint injection as the acupuncture technique, one of which also used electrical needling stimulation. The remaining study (Bai and Yu<sup>9</sup>) used traditional acupuncture in the treatment group.

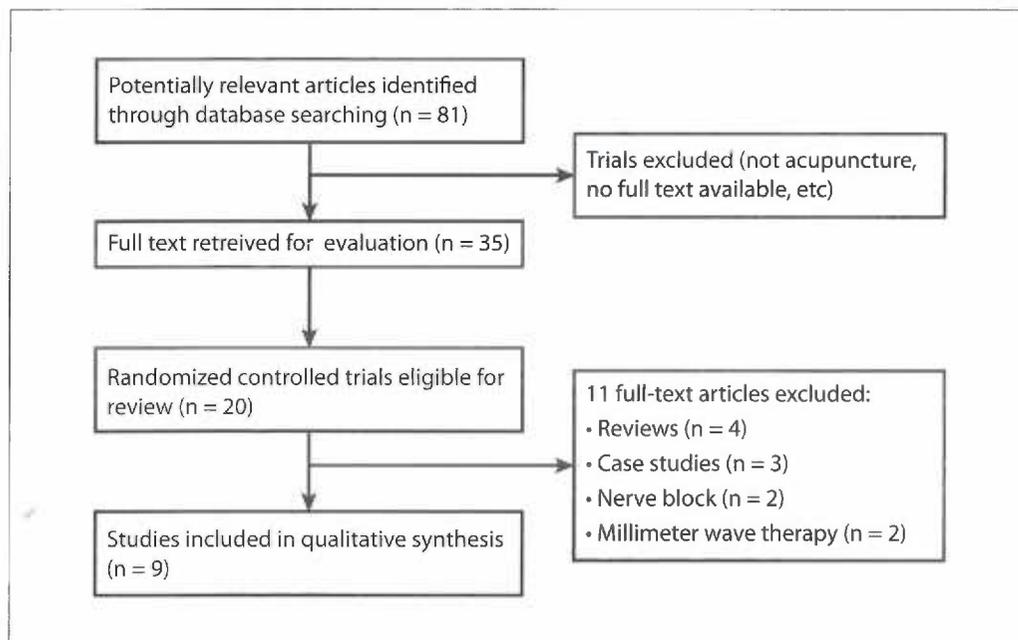


Fig 1 Article-selection process.

All studies reported at least one clinical-related outcome measurement (eg, pain and dry mouth). However, only one study<sup>10</sup> reported use of a visual analog scale to measure pain. The remaining trials reported the number of participants in the categories cured, marked improvement, improvement, or no effect.

**Intervention characteristics**

Study objectives varied among the studies. To determine its effectiveness, acupuncture was compared to different pharmacologic controls, including vitamins, traditional Chinese medicines, and acupuncture plus traditional Chinese medicines.

The most commonly used acupoints were LI4, LI11, and SI17. The treatment session ranged from 10 days to 3 weeks. The longest follow-up period was 3 months in two studies (Yong et al<sup>11</sup> and Li and Luo<sup>12</sup>).

De Qi was reported in two trials (Bai and Yu<sup>9</sup> and Huang and Huo<sup>13</sup>) as a phenomenon when the acupuncture point was reached. In traditional Chinese medicine, *de Qi* refers to the sensation felt when an acupuncturist reaches the acupoint at

the level of the qi (ie, vital energy) in the body. This sensation may feel like distention, throbbing, or an electrical impulse in the area of the acupoint being addressed. It is generally accepted that the action of a given acupuncture point is assured only when needling is accompanied by *de Qi*.

**Quality assessment**

Randomization, blindness, and withdrawals were insufficiently addressed in all nine studies, and a low quality was found for all studies (Jadad score < 3) (Table 1).

All studies divided the patients into two groups and used only a description such as “randomly divided into two groups” without further explanation (Jadad score, 1). Only one article<sup>14</sup> contained the additional explanation “by means of a random number table” (Jadad score, 2). None of the studies mentioned single blinding or double blinding (Jadad score, 0). In all trials, neither the number of lost cases (eg, dropouts, withdrawals, or protocol deviations) nor the reasons for such losses were reported (Jadad score, 0). None of the studies applied intention-to-treat analysis. No articles with “randomly divided into two groups” in their



**Table 1** Characteristics of the included trials

Study	Participants			Jadad score (0-5)	Treatment course	Intervention	
	n	Sex (% female)	Age (y) (mean ± SD)			Treatment	Control
Qiu <sup>14</sup>	200	60	51.3 ± 10.5 (mean ± SD)	2	10 d	Laser acupuncture	Acupoint injection
Bai and Yu <sup>9</sup>	70	100	40-65	1	20 d	Electric acupuncture	Oral oryzanol, vitamin B2, and vitamin E
Huang and Zong <sup>10</sup>	52	84.6	52.3 (mean)	1	20 d × 3	Acupoint injection	Oral oryzanol and vitamin B
Huang and Huo <sup>13</sup>	43	79.1	31-75	1	20 d	Acupoint injection	Oral oryzanol and vitamin E
Ma <sup>15</sup>	26	-	40-70	1	20 d	Acupoint injection	Oral oryzanol and vitamin B
Yong et al <sup>11</sup>	35	85.7	38-60	1	10 d × 5	Acupoint injection + oral oryzanol	Oral oryzanol
Mo and Liu <sup>16</sup>	38	-	43-72	1	20 d	Acupoint injection	Oral oryzanol and vitamin B
Lv and Li <sup>17</sup>	55	83.6	30-75	1	3 wk × 2	Acupoint injection	Oral oryzanol and vitamin B
Li and Luo <sup>12</sup>	28	78.6	43.29 (mean)	1	7 d × 12	Acupoint injection + oral oryzanol, vitamins B and E, and TCM	Oral oryzanol, vitamins B and E, and TCM

SD, standard deviation; TCM, traditional Chinese medicine.

abstracts reported the concealment measures of randomized allocation, and none reported the calculating basis of sample size.

**Therapeutic efficacy**

In seven of the trials, acupoint injection therapy was compared with medication as a treatment of BMS. In all seven trials, pain relief in the acupoint injection group was significantly greater than in the control group. The substance used in the acupoint injection was lidocaine accompanied by vitamin B (B1 and B12). The substance and dosage were consistent in all seven studies. Two studies (Yong et al<sup>11</sup> and Li and Luo<sup>12</sup>) applied acupoint injection with oral medication in the treatment group and oral medication only in the control group. Both studies found greater relief of pain and other symptoms in the acupoint injection group.

Qiu<sup>14</sup> compared acupoint injection with laser acupuncture and found a better response rate in the acupoint injection group. Bai and Yu<sup>9</sup> used traditional acupuncture in the treatment group and oral oryzanol and vitamin B2 in the control group.

They found better results in the acupuncture group than in the medication group. None of the nine trials reported the adverse effects related to acupuncture. Oryzanol is widely used in mainland China as an agent for the treatment of nerve imbalance and disorders of menopause. It has been approved in China and Japan for several conditions, including menopausal symptoms, mild anxiety, upset stomach, and high cholesterol. Its mechanism of action may include the antioxidant effect.<sup>18,19</sup>

**DISCUSSION**

BMS is a chronic intraoral mucosal pain condition often accompanied by xerostomia and taste disturbances. An incomplete understanding of the etiology and pathophysiology of the disease remains a barrier to effective treatment. There is limited evidence available to guide clinicians in the management of patients with BMS. While clonazepam and cognitive therapy have



Acupoint	De Qi sensation achieved	Diagnosis of BMS	Outcomes evaluated
TE17, SI17, ST4	Not reported	Exclusive	Oral symptoms and other somatic symptoms (rating score 1–5)
LI4, RN23, KI3, GV20, EX-HN12, EX-HN13	Yes	Exclusive	Pain relief, dry mouth, and other symptoms
BL20, BL17, BL23, SP10	Not reported	Exclusive	VAS for pain and symptoms
LI4, LI11, SI17	Yes	Exclusive	Burning pain, dry mouth, and sleep quality
TE17, RN23, ST4	Not reported	Exclusive	Pain and other symptoms
ST4, SI17, TE17	Not reported	Exclusive	Pain and taste change
ST4, SI17, TE17	Not reported	Exclusive	Pain and other symptoms
LI4, LI11, SI17	Not reported	Exclusive	Symptoms relief
KI3, SP6, ST36, PC6, TE5, SI17, LI11, LI4	Not reported	Exclusive	Pain and other symptoms

VAS, visual analog scale; BMS, burning mouth syndrome.

been proven effective in some patients, the treatment results are still not satisfactory. One systematic review<sup>20</sup> on BMS examined the use of antidepressants, cognitive behavioral therapy, analgesics, hormone replacement therapy, alpha-lipoic acid, and anticonvulsants. In the nine trials included in that review, none of the interventions examined demonstrated a significant reduction in BMS symptoms. Therefore, there is an urgent need to develop new therapeutic options to decrease the pain and other symptoms of BMS.

Acupuncture has been used as a clinical therapy for more than 5,000 years. It has been reported to promote pain relief, reduce inflammation, and enhance the immune system. According to the theory of traditional Chinese medicine, when pain occurs, the qi is blocked or out of balance. The pain stops when the qi moves.<sup>21</sup> The term *qi stagnation* refers to a pathologic change characterized by impeded circulation of qi that leads to stagnation of qi movement and functional disorder of the organs, manifested as pain in the affected area. Acupuncture is believed to correct this

imbalance and alleviate pain by regulating the blood flow of qi. Therefore, acupuncture is considered especially suited for the treatment of pain conditions, in which psychological, spiritual, and emotional issues may be involved along with any physical problems. Acupoint injection therapy (ie, water needling) is one acupuncture technique used to inject a medicated solution into an acupoint. It functions by provoking similar physiologic responses as acupuncture but may have more powerful clinical effects since it combines acupuncture and medication.<sup>22</sup>

Many studies have examined acupuncture in pain treatment, including postoperative dental pain,<sup>5,23</sup> fibromyalgia,<sup>24,25</sup> and head and neck pain.<sup>26</sup> However, few clinical trials were found regarding acupuncture for the treatment of BMS. In the present study, the authors searched electronic databases such as MEDLINE without language restrictions. No articles in a language other than Chinese were found. In the Chinese studies of acupuncture as a treatment for BMS, the conclusions were limited by the small number of subjects. Therefore, this systematic review aimed to evaluate the therapeutic



efficacy of acupuncture for the management of BMS. In the studies reviewed here, acupuncture was compared with a variety of control procedures, and various conclusions emerge. The effectiveness of acupuncture/acupoint injection therapy appeared to be satisfactory in most cases in terms of reducing pain, dry mouth, and other somatic symptoms. This finding agrees with previously published data regarding acupuncture and other pain conditions.<sup>4,27</sup>

The mechanism behind acupuncture in treating BMS remains unknown. One study proposed that acupuncture may reduce the burning sensation in BMS patients by influencing the oral microcirculation.<sup>28</sup> BMS patients in the study were treated with acupunctural techniques, and microcirculation was observed *in vivo* using videocapillaroscopy. It was shown that acupuncture influences oral microcirculation, resulting in a significant variation of the vascular pattern and a significant reduction of the burning sensation after therapy. This reduction of the burning sensation was maintained for 18 months following the acupuncture therapy. Therefore, the study considered acupuncture a valid treatment in the management of BMS.

The present study is the first systematic review to examine the therapeutic efficacy of acupuncture for BMS. In the nine trials included, acupuncture or acupoint injection was found to be effective as a treatment for BMS. The majority of the studies compared true acupuncture with medication therapy (oral oxyzanol and vitamin B2). However, there is still a lack of evidence regarding whether these medications are effective in treating BMS. Although pain and other symptoms were relieved in the 1- to 3-month durations of the trials, long-term outcomes still need to be considered.

There are several limitations to this review. First, the heterogeneity of study results is often considered a limitation in systematic reviews. The heterogeneity of the present review is variable due to the different acupuncture treatments and control designs.

Further, the placebo effect is an important consideration in the management of complex pain conditions such as BMS. Acupuncture may have a specific effect

beyond the placebo effect for BMS treatment; however, none of the included studies provided evidence of this by comparing acupuncture with sham controls. In recent years, there have been increasing reports on acupuncture therapy using sham controls in randomized clinical trials. There are several sham acupuncture techniques. One sham intervention, which can be used as a control specifically for acupoint therapy, uses body locations not recognized as true acupoints or meridians for needling (ie, sham needling). Another sham treatment, a control for needle insertion, consists of noninsertive simulated acupuncture at the same acupoints used in directed acupuncture (ie, simulated acupuncture). This technique, in which a toothpick in a needle guide tube is used to mimic needle insertion and withdrawal, has been shown to closely duplicate the needle insertion experience and to be indistinguishable from true acupuncture in acupuncture-naïve patients.<sup>29-31</sup>

Finally, the methodologic quality of the studies, as assessed by the modified Jadad score for clinical trials, was disappointing. Many studies lacked adequate blinding strategies. Therefore, high-quality studies with additional design features (eg, blinding, sham control, and standardization of the interaction between the acupuncturists) are required to verify the efficacy of acupuncture for the management of BMS.

## CONCLUSION

Studies in China supported the effectiveness of acupuncture for the management of BMS. However, high-quality randomized controlled trials are lacking. In light of the positive outcomes reported, the efficacy of acupuncture therapy in the treatment of BMS warrants further research.

# Six-month Efficacy of Perineural Dextrose for Carpal Tunnel Syndrome: A Prospective, Randomized, Double-Blind, Controlled Trial



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## Abstract

**Objective:** To assess the 6-month effectiveness of ultrasound-guided perineural injection therapy (PIT) using 5% dextrose (D5W) in patients with mild-to-moderate carpal tunnel syndrome (CTS).

**Patients and Methods:** A prospective, randomized, placebo-controlled, and double-blind study was conducted between May 1, 2016, through March 30, 2017. A total of 49 participants diagnosed with mild-to-moderate CTS were randomized into D5W and control groups. Participants in the D5W group received 1 session of ultrasound-guided PIT with 5 cc of D5W, and the control group received PIT with normal saline. The visual analog scale measured pain as a primary outcome. Secondary outcomes were Boston Carpal Tunnel Syndrome Questionnaire scores, the cross-sectional area of the median nerve, and electrophysiological measurement results. Assessment was performed before injection and at 1, 3, and 6 months post-injection.

**Results:** All patients (data from 30 wrists in each group) completed the study. Compared with the control group, at all post-injection time points, the D5W group had a significant reduction in pain and disability, improvement on electrophysiological response measures, and decreased cross-sectional area of the median nerve.

**Conclusion:** Our study reveals that ultrasound-guided PIT with D5W is an effective treatment for patients with mild-to-moderate CTS.

**Trial Registration:** [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov): NCT02809261.

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Carpal tunnel syndrome (CTS) is the most common focal entrapment neuropathy.

The etiology of CTS is unknown, but generally, it is believed to result from nerve damage resulting from compression of the median nerve (MN) in carpal tunnel-related gradual ischemia.<sup>1,2</sup> Therapeutic strategies for CTS range from conservative treatments (eg, medication, splinting, corticosteroid injection, and extracorporeal shock wave therapy) to surgical intervention. Although conservative approaches are beneficial for most patients who have mild-to-moderate CTS,<sup>3</sup> a large, population-based study reported that approximately 40% of conservatively treated patients sustained symptoms after 30 months.<sup>4</sup> Moreover, a Cochrane review<sup>5</sup> indicates that the effectiveness of conservative treatments is only short term; hence, development of new approaches for conservative management of mild-to-moderate CTS is critical.

Perineural injection therapy (PIT) is a novel technique that involves the injection of dextrose solutions into the peripheral nerve and has been found to provide promising pain-relief benefits.<sup>6-8</sup> Notably, 5% dextrose (D5W) has an osmolality similar to that of normal saline, and on injection is less painful than sterilized water.<sup>9</sup> Moreover, human and animal studies have found that D5W is not harmful to nerves.<sup>9-12</sup> In addition, D5W, unlike solutions of more than 10% dextrose, is useful in prolotherapy, a term that refers to treatment of various conditions associated with musculoskeletal pain.<sup>13,14</sup> Currently, in clinical practice, D5W is the most commonly used solution for PIT. However, few studies have investigated the efficacy of PIT for pain relief. Ultrasound-guided PIT, using corticosteroid in combination with lidocaine, is a treatment for releasing entrapments of the peripheral nerves, such as the MN,<sup>15,16</sup> the ulnar



**For editorial comment, see page 1173**

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nerve,<sup>17</sup> the lateral femoral cutaneous nerve,<sup>18,19</sup> the saphenous nerve,<sup>20</sup> and the sural nerve.<sup>21</sup> Although use of ultrasound-guided PIT in the clinical setting is increasing, only one instance of its use with D5W for an entrapment neuropathy has been reported.<sup>22</sup>

In the study reported here, we hypothesized that ultrasound-guided PIT with D5W is effective for treatment of CTS. We conducted an investigation of the 6-month effect of this treatment in patients who had mild-to-moderate CTS.

## MATERIALS AND METHODS

### Study Design

The present investigation was a prospective, randomized, placebo-controlled, and double-blind study conducted at a single medical center in Taiwan between May 1, 2016, through March 30, 2017. With the review and approval of the Institutional Review Board of Tri-Service General Hospital (No. 2-105-05-033), all enrolled participants provided written and fully informed consent. A total of 60 patients diagnosed with mild-to-moderate CTS were assessed for eligibility, and 49 were enrolled in our study. The patients were assigned to either a D5W group or a control group, using a block randomization (1:1 ratio) based on computer-generated random numbers in Microsoft Excel. The D5W patient group received 1 session of ultrasound-guided PIT, with 5 cc of D5W; the control group received ultrasound-guided PIT with 5 cc of normal saline. For patients who had bilateral CTS, both wrists were assigned to the same treatment group. All patients were prohibited from receiving

any other conservative management for CTS from 2 weeks before the start of participation to the end of the study. Only acetaminophen (500 mg up to 4 g daily) was allowed as a pain-relief agent. To ensure adherence to this restriction, a study nurse regularly followed up with patients.

### Inclusion and Exclusion Criteria

Patients who were diagnosed with mild-to-moderate CTS on the basis of an electrophysiological analysis, and who had onset symptoms that had persisted for at least 6 months, were considered for inclusion. The criteria for clinical symptoms and signs used for diagnosis are defined in Table 1. A diagnosis of CTS was assigned to patients who met inclusion criterion 1 and one or more of inclusion criteria 2-4.<sup>23,24</sup> Exclusion criteria are defined in Table 1 as well.<sup>25,26</sup>

### Electrophysiological Analysis and CTS

#### Grading

The diagnosis and grading of CTS were made on the basis of an electrophysiological study (Table 2).<sup>27-29</sup> Only patients who had mild-to-moderate CTS were recruited.

### Ultrasound-guided PIT

Ultrasound-guided injection was performed as previously described, using MyLab™25Gold(Esaote).<sup>26</sup> The MN was assessed at the proximal carpal tunnel inlet (ie, the scaphoid-pisiform level). The ultrasound-guided PIT, with 5 cc of either D5W or normal saline, was performed using an in-plane ulnar approach. A 3-ml injectate was used to remove the nerve from the flexor retinaculum via hydrodissection, and a residual

**TABLE 1. Inclusion and Exclusion Criteria**

#### Inclusion criteria

1. Paresthesia/dysesthesia; painful swelling with clumsy weakness of the hand, exacerbated by sleep or repetitive use of the wrist, and relieved by shaking the hand, with postural change
2. Sensory loss with numbness in the median nerve–innervated regions of the hand
3. Weakness with atrophy of the median nerve–innervated thenar muscles
4. Positive Phalen test and/or Tinel sign

#### Exclusion criteria

1. History of polyneuropathy, brachial plexopathy, or thoracic outlet syndrome
2. Previous wrist surgery or steroid injection for carpal tunnel syndrome

**TABLE 2. Electrophysiological Study and Grades of Carpal Tunnel Syndrome**

Cut-off points or normal value

1. Upper limit of distal latency of median sensory nerve  $\leq 3.6$  ms at a distance of approximately 14 cm from the active electrode
2. Upper limit of DML of the median nerve  $< 4.3$  ms at a distance of approximately 8 cm from the thenar muscle

Grade

3. Minimal: abnormal segmental or comparative tests only
4. Mild: abnormal digit/wrist sensory nerve conduction velocity only, with normal DML
5. Moderate: abnormal digit/wrist sensory nerve conduction velocity and abnormal DML
6. Severe: absence of sensory response and abnormal DML
7. Extreme: absence of motor and sensory responses

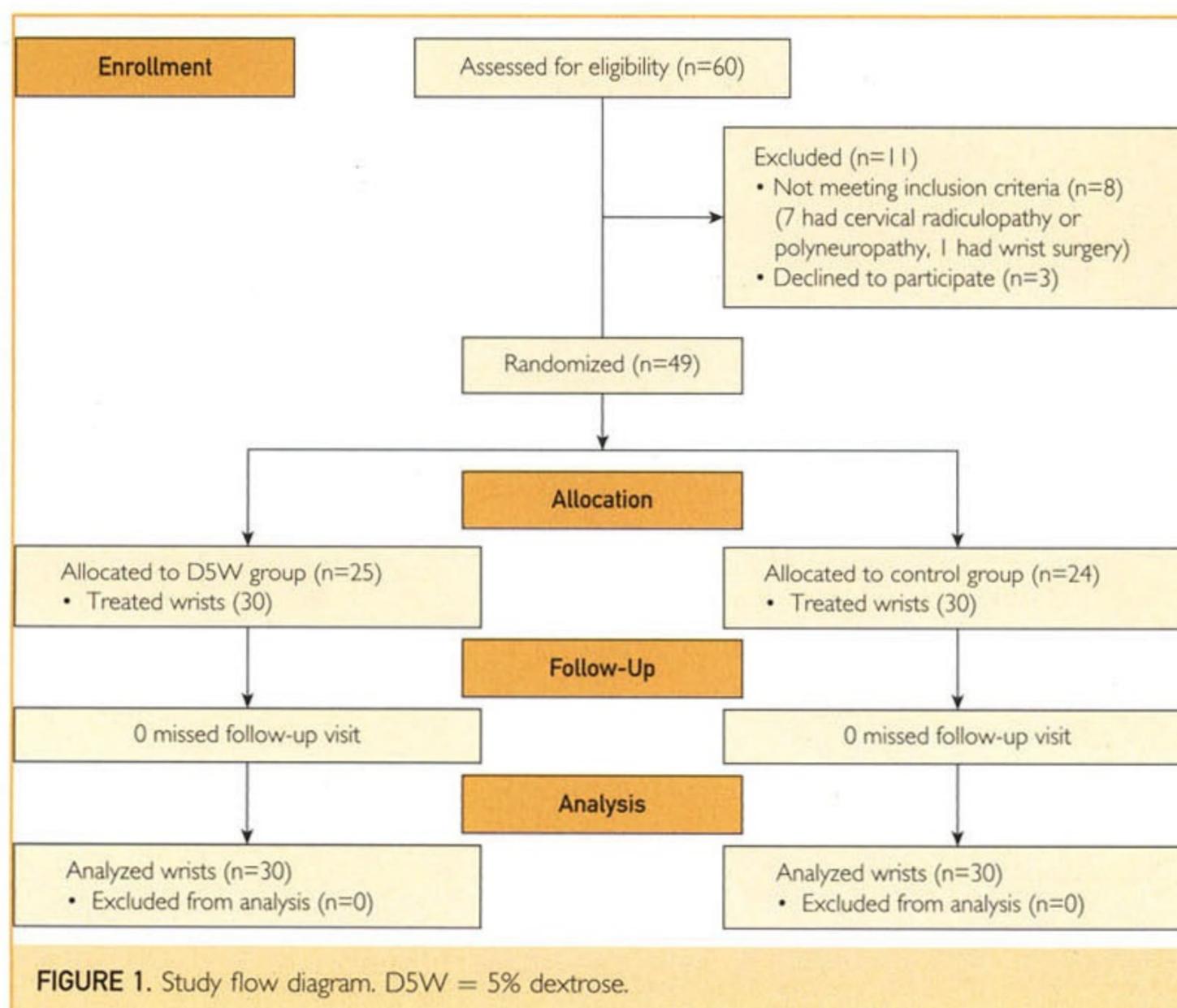
DML = distal motor latency.

2-ml injectate was delivered to the inferior part of the MN for separation from the underlying subsynovial connective tissue and flexor tendons. After injection, the whole carpal tunnel was scanned to ensure that the injectate was distributed throughout the proximal-to-distal carpal tunnel. Every patient was monitored for 30 minutes after injection for possible complications, such as bleeding and nerve trauma.

**Outcome Measurements**

The same physiatrist performed all outcome assessments, without knowledge of which group patients were in or the injectate content, at 1, 3, and 6 months post-injection, for comparison with pre-injection measures.

**Primary Outcome: Visual Analog Scale (VAS) Score.** The VAS was used to assess digital pain severity and paresthesia/dyesthesia



within 1 week before evaluation.<sup>26</sup> Scores ranged from 10 (extremely severe pain) to 0 (no pain) points.<sup>30</sup>

**Secondary Outcome: Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) Score.** The self-administered BCTQ includes 2 subscales of symptom severity (11 questions) and functional status (8 questions); it is the most commonly used measurement for CTS.<sup>31</sup> Scores range from 0 to 5 points for each question, with higher scores indicating greater severity and dysfunction.

**Secondary Outcome: Cross-sectional Area (CSA) of the MN.** The same physiatrist measured the CSA of the MN as described elsewhere.<sup>25,26</sup> In brief, the CSA was measured using an electronic caliper at the proximal inlet of the carpal tunnel (ie, at the scaphoid-pisiform level). The mean of 3 such measurements was used for analysis.

**Secondary Outcome: Electrophysiological Analysis Results.** The antidromic sensory nerve conduction velocity (SNCV) and distal

motor latency (DML) of the MN were measured in all patients as described elsewhere.<sup>26,32</sup> In brief, the SNCV was measured using a 14-cm stimulator that was proximal to the active electrode over the second interphalangeal joint. The DML was recorded via MN stimulation at 8 cm proximal to the active electrode over the abductor pollicis brevis muscle. An average of 3 such measurements was calculated.

**Secondary Outcome: Global Assessment of Treatment Results.** At the 3- and 6-month follow-up assessments, symptom relief after injection was evaluated for all patients and categorized as one of the following: much improved, improved, no change, worse, or much worse. Patients in the category of much improved or improved were considered to have had effective treatment.

#### Sample Size

A preliminary power analysis using G\*power 3.1.9.2 (University of California, Los Angeles) was calculated in a repeated-measures 1-way analysis of variance for comparison of 2 groups. For an effect size ranging from

**TABLE 3. Baseline Demographic and Clinical Characteristics of Study Participants<sup>a</sup>**

Characteristic	5% dextrose group (n=30)	Control group (n=30)	P value <sup>b</sup>
Age (y)	58.47±2.33	58.10±1.93	.90
Body height (cm)	158.13±1.20	160.17±1.01	.20
Body weight (kg)	65.13±1.69	62.77±1.35	.28
Diabetes mellitus	2 (6.67)	4 (13.33)	.67
Hypertension	14 (46.67)	16 (53.33)	.80
Gender			.73
Male	4 (13.33)	6 (20.00)	
Female	26 (86.67)	24 (80.00)	
Duration (mo)	44.57±7.54	44.47±5.53	.99
Lesion site			.61
Right	17 (56.67)	14 (46.67)	
Left	13 (43.33)	16 (53.33)	
Grading (Padua)			.99
Moderate	19 (63.33)	18 (60.00)	
Mild	11 (36.67)	12 (40.00)	
Visual analog scale	6.67±0.30	6.56±0.30	.81
Boston Carpal Tunnel Syndrome Questionnaire score			
Severity	30.20±1.25	28.07±1.93	.36
Function	21.87±0.69	19.93±0.96	.11
Sensory nerve conduction velocity (m/s)	33.76±1.01	33.83±0.90	.96
Distal motor latency (ms)	4.89±0.24	4.68±0.15	.45
Cross-sectional area (mm <sup>2</sup> )	12.36±0.35	12.29±0.36	.89

<sup>a</sup>Values are given as No. (%), or ± standard error.

<sup>b</sup>P value obtained from independent t-test for continuous data, and  $\chi^2$  test/Fisher exact test for categorical data.

0.5 to 0.25, data for at least 16 to 54 wrists were required to achieve sufficient power [(1-β)=0.95; α=0.05].<sup>33</sup>

**Statistical Analyses**

All data were analyzed using IBM SPSS software, version 22. Demographic data were analyzed using an independent *t*-test for continuous data, and a  $\chi^2$  test or Fisher exact test for categorical data. A repeated-measures analysis of variance and a subsequent post hoc test were used for analysis of the follow-up data. An independent *t*-test was performed to compare differences between groups, including VAS scores, BCTQ scores, CSA of MN measurements, electrophysiological study

results, and global assessment results. All statistical tests were 2-tailed; a *P* value of less than .05 was considered statistically significant.

**RESULTS**

A total of 49 participants completed the study, yielding data from 30 wrists in each group (Figure 1). Clinical characteristics of the participants did not differ between groups (Table 3; all *P*>.05). The mean duration of symptom onset was 44.57±7.54 and 44.47±5.53 months in the D5W and control groups, respectively. More than 60% of the wrists in each group had a moderate CTS grade. Table 4 presents the VAS and BCTQ

TABLE 4. All Measurements in Both Groups, Before and After Injection <sup>a</sup>				
	5% dextrose group (n=30)		Control group (n=30)	
	Mean ± standard error	<i>P</i> value	Mean ± standard error	<i>P</i> value <sup>b</sup>
Visual analog scale score				
Before injection	6.67±0.30		6.56±0.30	
M1	4.60±0.35	<.001	5.64±0.35	.002
M3	3.57±0.30	<.001	4.70±0.46	<.001
M6	2.43±0.30	<.001	4.59±0.46	<.001
Boston Carpal Tunnel Syndrome				
Questionnaire score—severity				
Before injection	30.20±1.25		28.07±1.93	
M1	20.83±1.06	<.001	22.37±1.76	<.001
M3	17.60±0.80	<.001	20.50±2.02	<.001
M6	15.30±0.60	<.001	21.60±2.06	.002
Boston Carpal Tunnel Syndrome				
Questionnaire score—function				
Before injection	21.87±0.69		19.93±0.96	
M1	14.17±0.72	<.001	18.00±1.05	.09
M3	12.90±0.52	<.001	16.77±1.18	.005
M6	11.43±0.46	<.001	17.07±1.23	.03
Sensory nerve conduction velocity (m/s)				
Before injection	33.76±1.01		33.83±0.90	
M1	35.46±1.17	.04	34.08±0.91	.99
M3	36.29±1.06	.003	33.72±1.03	.99
M6	36.75±1.19	.004	34.08±1.04	.99
Distal motor latency (ms)				
Before injection	4.89±0.24		4.68±0.15	
M1	4.68±0.23	.22	4.72±0.15	.99
M3	4.64±0.22	.20	4.72±0.15	.99
M6	4.53±0.20	.43	4.64±0.16	.99
Cross-sectional area (mm <sup>2</sup> )				
Before injection	12.36±0.35		12.29±0.36	
M1	11.00±0.33	<.001	11.32±0.37	<.001
M3	10.53±0.31	<.001	11.22±0.37	<.001
M6	10.26±0.35	<.001	11.11±0.38	<.001

<sup>a</sup>M = month.  
<sup>b</sup>*P* value obtained from repeated-measures analysis of variance and subsequent post hoc test.

scores, electrophysiological results, and the CSA of the MN, before and after injection. The VAS and BCTQ scores and CSA measurements in both groups indicated notable improvement at all follow-up time points, compared with baseline measures (all  $P < .05$ ; not including the first-month BCTQ function of the control group [ $P = .08$ ]). For the electrophysiological analysis, only the SNCV results for the D5W group were significant at all follow-up time points, compared with baseline ( $P < .05$ ), although we observed a tendency toward improvement in the DML of the D5W group at follow-up time points further from injection.

Compared with the scores of the control group, at all follow-up time points, the D5W group scores for VAS, BCTQ severity, and BCTQ function (all scores reported as D5W group vs control group, respectively) revealed significant improvement. For VAS (Figure 2), scores were:  $-2.07 \pm 0.24$  vs  $-0.93 \pm 0.21$  at 1 month;  $P = .001$ ;  $-3.10 \pm 0.35$  vs  $-1.86 \pm 0.37$  at 3 months;  $P = .02$ ; and  $-4.23 \pm 0.33$  vs  $-1.98 \pm 0.37$  at 6 months;  $P < .001$ . For BCTQ severity (Figure 3A),

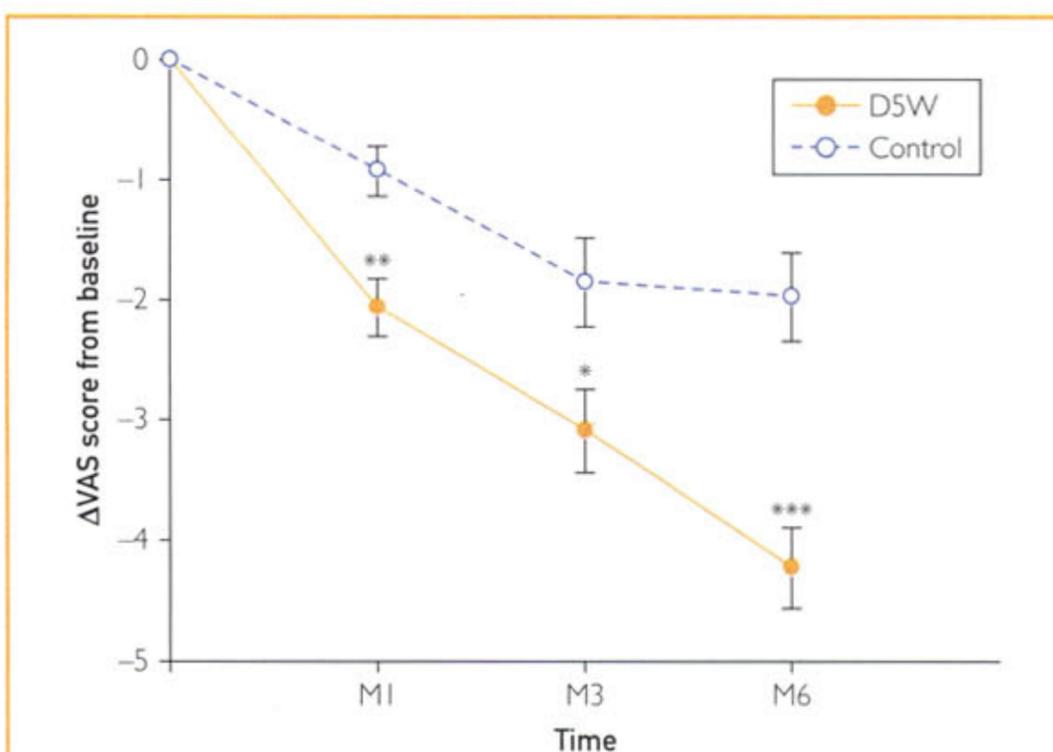
scores were:  $-9.37 \pm 1.20$  vs  $-5.70 \pm 0.93$  at 1 month;  $P = .02$ ;  $-12.60 \pm 1.19$  vs  $-7.57 \pm 1.54$  at 3 months;  $P = .01$ ; and  $-14.90 \pm 1.24$  vs  $-6.47 \pm 1.46$  at 6 months;  $P < .001$ . For BCTQ function (Figure 3B), scores were:  $-7.70 \pm 0.97$  vs  $-1.93 \pm 0.65$  at 1 month;  $P < .001$ ;  $-8.97 \pm 0.73$  vs  $-3.17 \pm 0.79$  at 3 months;  $P < .001$ ; and  $-10.43 \pm 0.83$  vs  $-2.87 \pm 0.86$  at 6 months;  $P < .001$ . These effects became more pronounced as the follow-up duration increased.

The SNCV, DML, and CSA differences between the 2 groups were also significant (Table 5), with the exception of (D5W group vs control group, respectively) the DML at 6 months ( $-0.37 \pm 0.20$  ms vs  $-0.04 \pm 0.07$  ms;  $P = .12$ ) and the CSA at 1 month ( $-1.37 \pm 0.19$  mm<sup>2</sup> vs  $-0.97 \pm 0.13$  mm<sup>2</sup>;  $P = .09$ ). In addition, 70% (21 of 30) and 50% (15 of 30) of patients scored a grade of either much improved or improved at the follow-up at 3 months in the D5W and control groups, respectively ( $P = .11$ ). These proportions increased to 76% (23 of 30) and 40% (12 of 30), respectively, at the follow-up at 6 months ( $P = .004$ ; data not shown). No adverse effects, complications, or nerve trauma were observed in either group. All patients reported that they had not received any extra medication or treatment during the study.

## DISCUSSION

The present study is the first prospective, randomized, double-blind, placebo-controlled study to investigate the benefit of ultrasound-guided PIT with D5W for mild-to-moderate CTS. Compared with controls, the D5W group exhibited a significant reduction in pain and disability, an improved electrophysiological response, and a decreased CSA of the MN for 6 months after treatment.

The D5W solution is the most commonly used injectate for PIT; however, to date, only 2 case series studies and 1 small clinical trial of D5W use have been reported.<sup>6-8</sup> Kim et al<sup>6</sup> reported that at a follow-up at 7 days, myofascial trigger-point injection therapy with D5W was superior to that using lidocaine or normal saline. Dufour et al<sup>12</sup> first used ultrasound-guided circumferential PIT with D5W at the MN before an intravascular local anesthetic injection for elbow surgery. They reported that additional D5W did not change the amount of



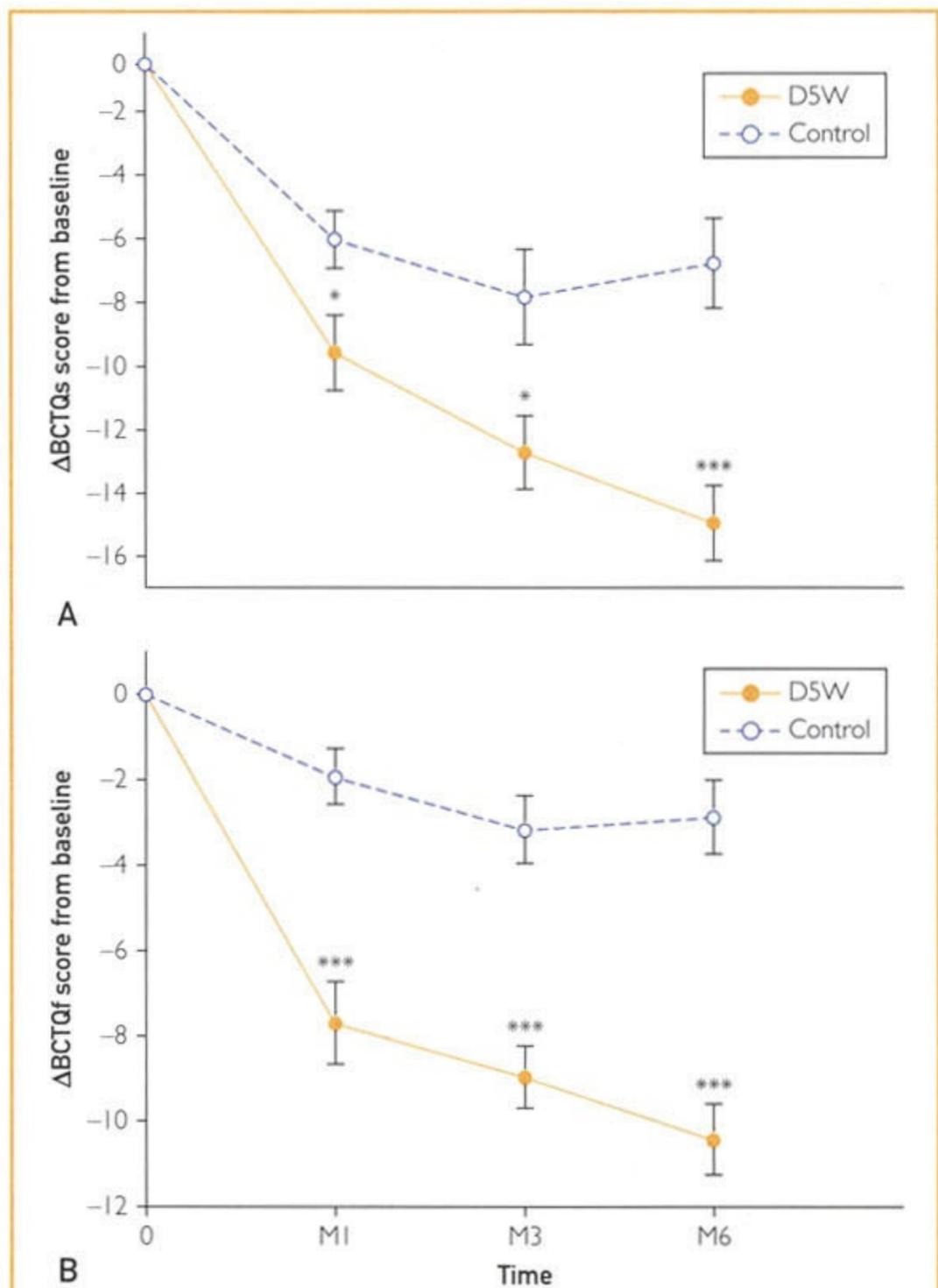
**FIGURE 2.** Mean change at baseline and post-injection in visual analog scale results in both groups (mean  $\pm$  standard error). The visual analog scale scores were significantly lower in the 5% dextrose group than in the control group, at all follow-up assessments ( $P < .05$ ), and this reduction became more pronounced as the follow-up duration increased. \* $P < .05$ ; \*\* $P < .01$ ; \*\*\* $P < .001$ ; an independent t-test was used. D5W = 5% dextrose; M = month; VAS = visual analog scale.

time before anesthesia was needed. Unfortunately, the therapeutic effect of D5W was not measured in their study. Although physicians increasingly use PIT, the use of ultrasound-guided PIT with D5W rarely has been reported.<sup>22</sup> Chang et al<sup>22</sup> first used ultrasound-guided PIT with D5W to treat a case involving entrapment of the superficial radial nerve branch, but they did not report the duration of therapy. Our systematic study is the first to report the effectiveness of PIT with D5W for peripheral entrapment neuropathy.

The mechanism underlying the effects of PIT with D5W is unknown and may be multifactorial. Dextrose can reduce neurogenic inflammation via the inhibition of capsaicin-sensitive receptors (eg, transient receptor potential vanilloid receptor-1) to stop the secretion of both substance P and calcitonin gene-related peptide, which are known to induce pain and swelling of the nerve and/or surrounding tissue.<sup>34-39</sup> However, various concentrations of dextrose have been used, and no study has specifically investigated the mechanism of D5W treatment. Future studies should use a histological analysis of a CTS animal model.

Nerve hydrodissection may also contribute to the therapeutic effects of D5W. Nerve hydrodissection is used to avoid nerve trauma and detach soft tissues, increasing the passage of nerve impulses and limiting ischemic nerve damage.<sup>26,40</sup> Recently, hydrodissection was used to assist ultrasound-guided nerve injection with corticosteroid in combination with lidocaine or platelet-rich plasma in patients who have CTS,<sup>15,16,26</sup> cubital tunnel syndrome,<sup>17</sup> meralgia paresthetica,<sup>18,19</sup> or infrapatellar saphenous neuralgia.<sup>20</sup> Although hydrodissection is used pervasively in clinical practice, hydrodissection research has involved only a small number of participants, or has lacked a control group or randomization, leading to selection bias. In addition, most of the analgesic improvement could result from the well-established analgesic effect of corticosteroid, lidocaine, and platelet-rich plasma.<sup>26,41</sup> Hence, the effect of and optimal time point for performing nerve hydrodissection are currently unknown.<sup>40</sup>

Our study design, which includes a consistent injection procedure and injectate volume, could eliminate the confounding effects of hydrodissection. In addition, our control group



**FIGURE 3.** Mean difference at baseline and post-injection in Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) scores in both groups (mean  $\pm$  standard error). (A) The BCTQ (severity) scores were significantly lower, indicating improvement, in the 5% dextrose group, compared with the control group, at all follow-up assessments ( $P < .05$ ). (B) The BCTQ (function) scores were significantly lower, indicating improvement, in both groups, at all follow-up assessments ( $P < .001$ ). All differences became more pronounced as the follow-up duration increased. \* $P < .05$ ; \*\* $P < .01$ ; \*\*\* $P < .001$ ; an independent  $t$ -test was used. BCTQf = BCTQ function; BCTQs = BCTQ severity; D5W = 5% dextrose; M = month.

was treated with normal saline because it has no pharmacologic effect on nerves. The effects we report persisted for 6 months, indicating the substantial efficacy of only 1 session of D5W treatment for mild-to-moderate CTS. Further, the improvement reflected by VAS and BCTQ scores, electrophysiological responses, and CSA in the D5W group, compared with the

**TABLE 5. Between-Group Comparison of Pretreatment Changes in Electrophysiological Study Results and Cross-sectional Area<sup>a</sup>**

	5% dextrose group (n=30)	Control group (n=30)	P value <sup>b</sup>
	Mean difference ± standard error	Mean difference ± standard error	
Sensory nerve conduction			
velocity (m/s)			
M1	1.70±0.58	0.25±0.29	.03
M3	2.53±0.65	-0.11±0.32	.001
M6	2.98±0.79	0.25±0.33	.003
Distal motor latency (ms)			
M1	-0.22±0.10	0.03±0.06	.04
M3	-0.26±0.11	0.03±0.05	.03
M6	-0.37±0.20	-0.04±0.07	.12
Cross-sectional area (mm <sup>2</sup> )			
M1	-1.37±0.19	-0.97±0.13	.09
M3	-1.83±0.24	-1.07±0.16	.01
M6	-2.11±0.26	-1.18±0.18	.004

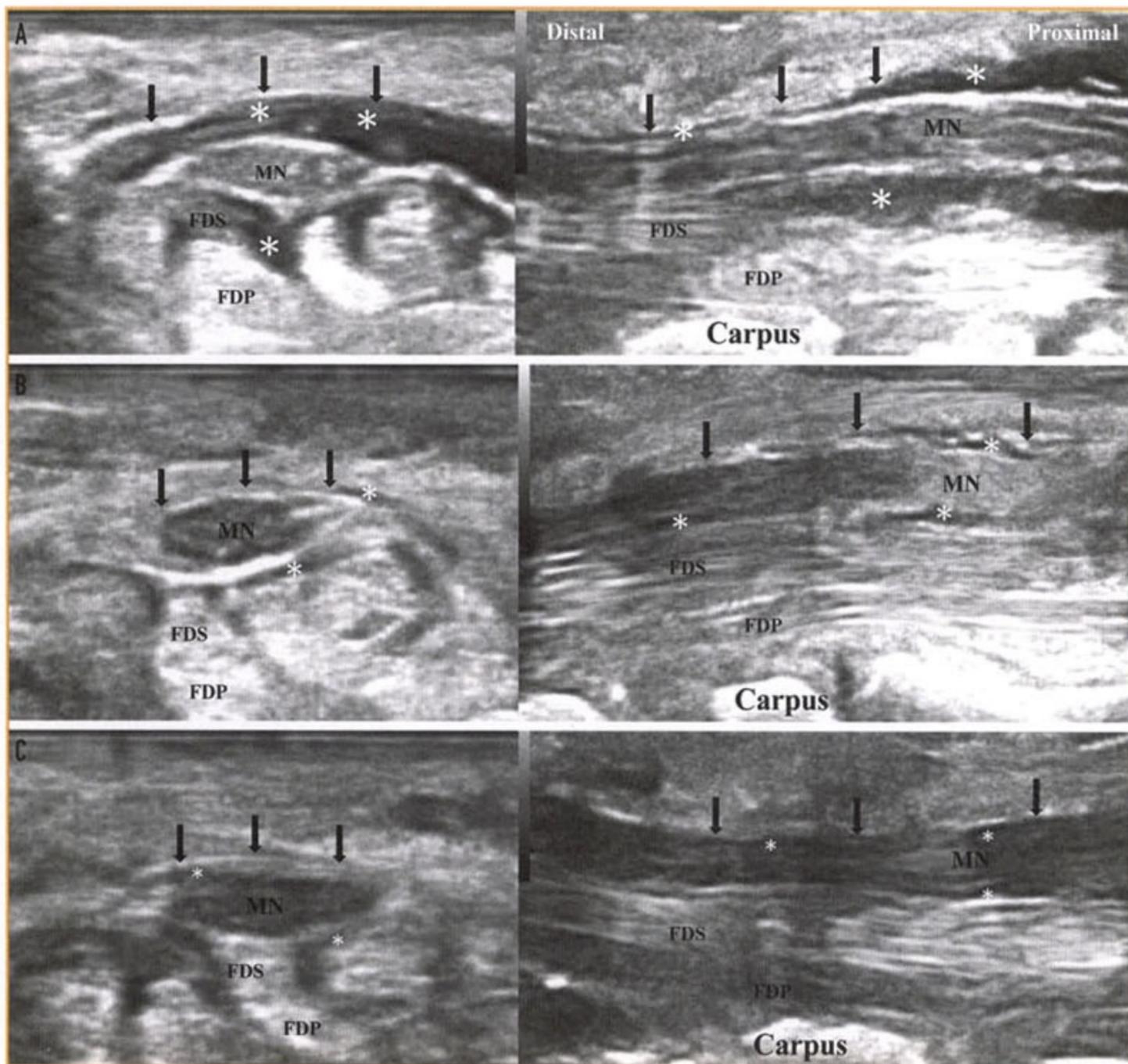
<sup>a</sup>M = month.  
<sup>b</sup>P value was obtained from independent t-test.

baseline time point and control group, appeared to increase with follow-up (Table 5; Figures 2 and 3). The effects of our D5W treatment likely would be maintained with further follow-up. Compared with corticosteroid (the most popular injectate for CTS), D5W can be used for a longer period and with fewer adverse effects; an evidence-based study reported that local corticosteroid injection was effective for only 1 month for CTS, compared with placebo control.<sup>41</sup> These 2 injectates should be compared in future studies.

We found considerable improvement in VAS, BCTQ, and CSA results in the control group, compared with baseline, suggesting that the therapeutic effect of 1 session of nerve hydrodissection with normal saline persists for 6 months. However, a placebo effect associated with injection, and spontaneous remission of CTS, could have occurred. Some randomized clinical trials have used a blind design to investigate the effects of corticosteroid injection for CTS compared with a normal saline or lidocaine control. The reported placebo effects for these studies ranged from 20% (10 mg lidocaine, follow-up assessment at 1 month) to 34% (1 cc normal saline + 1 cc lidocaine, follow-up assessment at 2 weeks).<sup>42,43</sup> Three trials have used only normal saline with a blind injection of a control group. Karadaş et al<sup>44</sup> did not observe any improvement with 1 cc of normal saline.

Peters-Veluthamaningal et al<sup>45</sup> found that 5 of 33 (15%) patients exhibited a satisfactory partial response at a follow-up assessment at 1 week after a 1-cc normal saline injection. Girlanda et al<sup>46</sup> reported notable improvement in nocturnal paresthesia and motor action potential at up to 2 months after a 15-mg normal saline injection (9 mg/cc; 2 injection sessions with a 1-week intervening interval).

The effect of normal saline injection in our study was longer and more pronounced, compared with the effects in the aforementioned research, possibly owing to differences in the guided method or injectate volume. Our study was the first to use ultrasound-guided injection with normal saline for the control group, and the 5 cc of injectate was a greater volume than that used in previous studies. A direct compression of the transverse carpal ligament at the MN induces CTS, and CTS subsequently induces inflammation of the intracarpal tendon. This condition commonly causes a cycle of swelling within the carpal tunnel and further compresses the MN.<sup>47</sup> Moreover, compared with blind injection, ultrasound-guided nerve hydrodissection is better for removing surrounding tissues from the MN, especially the intracarpal tendons. Nevertheless, 34% of untreated patients can spontaneously improve after 10-15 months of follow-up.<sup>48</sup> For our patients, the mean duration of



**FIGURE 4.** Follow-up ultrasonography imaging after injection (left: transverse view; right: long axial view). (A) Immediately after injection: The injectate (\*) can be observed between the flexor retinaculum (arrows), median nerve, and flexor tendons. (B) Thirty minutes after injection: Most injectate (\*) is absorbed. (C) One hour after injection: The injectate (\*) is completely absorbed. FDP = flexor digitorum profundus; FDS = flexor digitorum superficialis; MN = median nerve.

symptom onset for both groups was 44 months, and the rate of spontaneous remission was relatively low. Most were first diagnosed with CTS at the time of our study and therefore retain the potential for spontaneous remission. We observed that the injectate was completely absorbed at 1 hour after injection, followed by ultrasonography (Figure 4). Consequently, the effects of 1-session nerve hydrodissection with normal saline could have been overestimated in our study. We are conducting a double-blind study, using an ultrasound-guided subcutaneous injection of normal saline for control participants, to investigate the effects of nerve hydrodissection.

**Limitations**

Our study has some limitations. First, we did not evaluate the mechanism of the effects of D5W. Second, we were not able to determine the influence or most appropriate timing of nerve hydrodissection. Our ongoing clinical trials with a sham-controlled design may provide relevant information. Finally, the optimal dosage and number of PIT sessions is unknown, so further studies are needed.

**CONCLUSION**

Our study reveals that ultrasound-guided PIT with D5W is a simple, safe, and effective treatment for mild-to-moderate CTS. Moreover,

this technique may be valuable for treating neuropathic pain and other peripheral entrapment neuropathies.

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**Abbreviations and Acronyms:** BCTQ = Boston Carpal Tunnel Syndrome Questionnaire; CSA = cross-sectional area; CTS = carpal tunnel syndrome; D5W = 5% dextrose; DML = distal motor latency; MN = median nerve; PIT = perineural injection therapy; SNCV = sensory nerve conduction velocity; VAS = visual analog scale

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## CASE STUDY

# Acupuncture and Trigger Point Injections for Fibromyalgia: East-West Medicine Case Report

Lawrence B. Taw, MD, FACP; Eve Henry, MD

## ABSTRACT

Fibromyalgia is a clinical syndrome characterized by chronic widespread pain that is often accompanied by  $\geq 1$  concomitant symptoms (eg, fatigue, poor sleep, cognitive alterations, and mood disturbances). In 2005, an estimated 5 million people in the United States suffered from fibromyalgia, and its growing effect on health-related quality of life is substantial. An increasingly popular hypothesis proposes that noxious, peripheral sensory input might contribute to the initiation and perpetuation of the diffuse pain seen in patients with

fibromyalgia. That theory has led to the evaluation of multiple interventions to stimulate distal areas as a means to modulate the peripheral and central nervous systems. It has been the authors' experiences that the combination of trigger point injections and acupuncture provides improved clinical outcomes. In the current article, the authors present a case report of a patient with fibromyalgia who was successfully treated with an integrative approach that combined acupuncture with trigger point injections. (*Altern Ther Health Med.* 2016;22(1):58-61.)

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**F**ibromyalgia is a chronic pain condition that is challenging to treat and increasing in prevalence. It is a clinical syndrome characterized by chronic widespread pain that is often accompanied by 1 or more concomitant symptoms, including fatigue, poor sleep, cognitive alterations, and mood disturbances.<sup>1,2</sup> In 2005, an estimated 5 million people in the United States suffered from fibromyalgia,<sup>3</sup> and its growing effect on health-related quality of life is substantial.<sup>4,5</sup>

Because the exact etiology of fibromyalgia is unknown, treatment is often directed at symptom control. Medications are commonly used first; however, their use is often limited by adverse effects, which has led many medical practitioners to consider employing a more comprehensive, multidisciplinary approach to improve outcomes.

Although the underlying pathophysiology of fibromyalgia has yet to be completely elucidated, a rising consensus exists that fibromyalgia is the result of aberrant pain sensitization.<sup>6</sup> Functional magnetic resonance imaging (MRI) studies have demonstrated that patients with fibromyalgia have increased neuronal activation of the pain processing regions of the cerebral cortex after the application of otherwise innocuous stimuli.<sup>7,8</sup>

Considerable evidence suggests that peripheral nociceptive input may be involved in the initiation and maintenance of the sensitization of the central nervous system (CNS) that is seen in patients with fibromyalgia.<sup>9,10</sup> Resolution of peripheral pain has also been documented to have widespread, systemic effects in fibromyalgia patients. Studies have demonstrated that deactivation of a local tender point not only significantly increased local pain thresholds but also decreased heat and pain sensitivity at distant anatomical sites in patients with fibromyalgia.<sup>11</sup>

The increasingly popular hypothesis that noxious, peripheral sensory input may contribute to the initiation and perpetuation of the diffuse pain seen in patients with fibromyalgia has led to the evaluation of multiple interventions, such as trigger point injections and acupuncture to stimulate distal areas as a means to modulate the peripheral and central nervous systems.<sup>6</sup>

### FIBROMYALGIA AND TRIGGER POINTS

Myofascial trigger points are small regions of intense tenderness and hyperirritability in muscles or their fascia.<sup>12</sup> Multiple studies have documented the presence of active trigger points in patients with fibromyalgia, consistent with the idea that those patients have coexisting myofascial pain syndrome.<sup>13,14</sup> A recent study described how manual manipulation of active trigger points reproduced the overall, spontaneous pain pattern experienced by patients with fibromyalgia, suggesting that referred pain from trigger points may account for a significant portion of the widespread pain in patients.<sup>15</sup>

Trigger point injections are often used in patients with fibromyalgia to deactivate trigger points, which may be indicated by a local twitch response, and the injections are associated with a decrease in pain symptoms and localized hypersensitivity.<sup>16</sup> A prospective study has demonstrated that fibromyalgia patients who received trigger point injections had significant improvement in experienced pain intensity, higher pain thresholds, and improved ranges of motion at 2 weeks after the injections.<sup>17</sup>

### FIBROMYALGIA AND ACUPUNCTURE

A significant anatomical correlation exists between musculoskeletal trigger points and acupuncture points. Melzack et al<sup>18</sup> reported more than a 70% correspondence between acupuncture points and trigger points. Further analysis has suggested that many of the trigger points identified in fibromyalgia patients could be considered to be *ah-shi* points (ie, tender and clinically relevant acupuncture points), bringing the correlation closer to 100%.<sup>19</sup> This overlapping relationship suggests that the benefit observed with trigger point injections may be related to the selection and stimulation of points using the concepts of acupuncture.

Numerous research studies have demonstrated the profound analgesic effect that acupuncture can have for patients with pain symptoms.<sup>20,21</sup> Indications of the involvement of the peripheral and central nervous systems in the underlying mechanism of acupuncture have been present since the mid- to late-20th century.<sup>22</sup> A growing body of evidence suggests that neuropeptides, such as endorphins in the CNS, may be mobilized by stimulation of the peripheral nervous system through acupuncture.<sup>23,24</sup> Further studies have demonstrated that the analgesic effects of acupuncture can be transferred between animals through cross-infusion of cerebrospinal fluid (CSF) into the third ventricle, and acupuncture induced analgesia can be reliably

negated through infusion of the opiate antagonist naloxone.<sup>25</sup>

Although research on the efficacy of acupuncture in patients with fibromyalgia has been mixed, a number of studies have demonstrated decreased pain and improved quality of life after multiple acupuncture treatments. A recent case series established that acupuncture performed specifically at tender points, significantly decreased pain and improved quality of life, as measured by the Fibromyalgia Impact Questionnaire, the Beck Depression Inventory, and the Beck Anxiety Inventory.<sup>26</sup> One recent systematic review<sup>27</sup> of published data found 3 randomized clinical trials that demonstrated a positive clinical effect for acupuncture with fibromyalgia patients.<sup>28-30</sup>

In the current article, the authors present a case report of a patient with fibromyalgia who was successfully treated with an integrative approach that combined acupuncture with trigger point injections.

### CASE REPORT

A 54-year-old female visited the authors' clinic with a 14-month history of diffuse body aches that extended from her neck down to her feet, extreme fatigue, insomnia, a sensation of lightheadedness, and multiple chemical sensitivities. Her symptoms had led her to visit 3 academic institutions and 12 medical specialists. She had been given a diagnosis of fibromyalgia by her rheumatologist based on the 1990 American College of Rheumatology (ACR) criteria for the classification.<sup>31</sup>

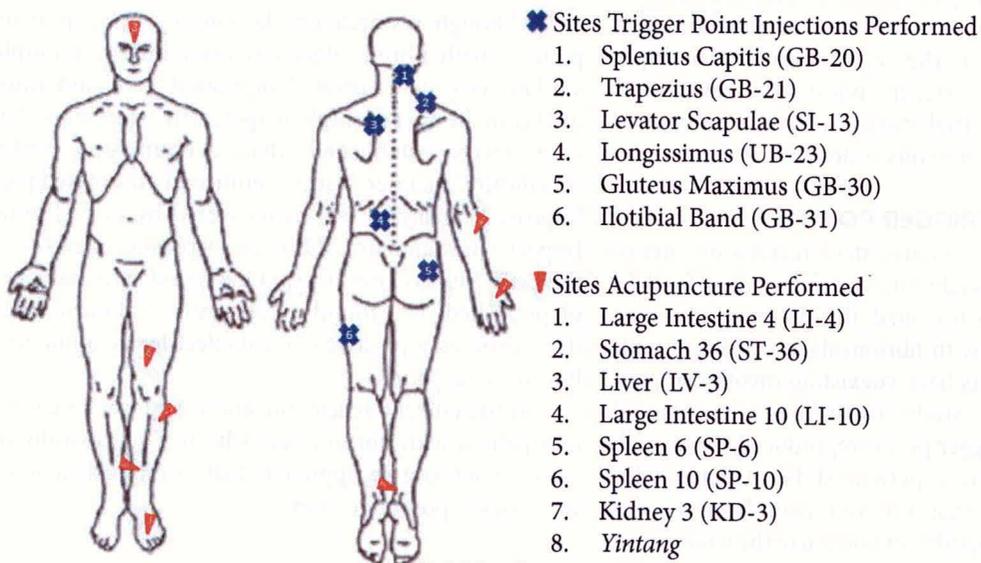
The woman was initially given venlafaxine and acetaminophen to help manage her symptoms from fibromyalgia. Because she had poor-quality sleep and was not able to perform aerobic or aquatic exercises due to severe fatigue, she was also advised to start sodium oxybate. Unfortunately, with the new medication, she experienced significant adverse effects that required hospitalization. Hypersensitivity to pharmaceutical agents prompted her to avoid use of further medications for fibromyalgia and to pursue a holistic approach that incorporated more natural therapies. She then visited the authors' clinic.

At the time of her evaluation, she was markedly stressed by her prolonged illness. A detailed history was obtained, and the patient's prior evaluations and work-ups, including blood tests and imaging studies, were reviewed with her. No structural or biochemical abnormalities were identified as the source of her prolonged symptoms.

A complete physical exam was then performed, which revealed tight, palpable muscle bands along her neck, back, and gluteal regions and thighs bilaterally. A combination of trigger point injections and acupuncture was performed on a weekly basis for 8 visits. After palpation for active trigger points, treatment was initiated with trigger point injections into the various local muscle groups (Figure 1).

The areas to be injected were prepared with alcohol using a sterile technique. A 23-gauge, 2.5-cm needle was

**Figure 1.** Sites used for trigger point injections and acupuncture.



Note: Points may be bilateral.

introduced into the taut muscle bands, often provoking a twitch response. Then 0.3 to 0.5 cm<sup>3</sup> of 1% lidocaine was injected into each active trigger point. After the injection, the needle was removed while pressure was applied to minimize the risk for bruising.

The patient was then placed in a comfortable resting position to allow acupuncture to be performed on points that had not yet been deactivated by the trigger point injections. Point prescriptions varied with each visit but often incorporated key distal points, such as Large Intestine 4 (LI-4) and Large Intestine 10 (LI-10), Liver 3 (LIV-3), Stomach 36 (ST-36), Spleen 6 (SP-6) and Spleen 10 (SP-10), Kidney 3 (KD-3), and *Yintang* (Figure 1). Each point was manually stimulated until the *deqi* sensation was elicited. Needles were left in place for 20 minutes and then removed.

In the course of her treatments, the patient experienced significant improvement in sleep quality, together with decreased pain, fatigue, and lightheadedness. She discontinued use of venlafaxine and acetaminophen, and, further, was able to work full time as a business analyst, exercise, travel regularly, and resume her active lifestyle. At a recent visit to the authors' clinic 4 years after initiation of treatment, she reported being able to maintain her desired level of activity and was receiving regular maintenance treatments once or twice per month.

## DISCUSSION

As in the case with the patient described in the aforementioned report, a significant number of patients with fibromyalgia pursue complementary and alternative medicine as part of their comprehensive treatment program due to an inadequate response to allopathic medicine, adverse effects from conventional care, or patient preference for more natural therapies.<sup>32</sup> Consistent with the 1990 ACR criteria for

classification of fibromyalgia, this patient had multiple active trigger points. Based on the common features of point location and pain modulation through its proposed effects on the peripheral and central nervous systems, these points were readily identified and effectively deactivated using a combination of acupuncture and trigger point injections.

## CONCLUSIONS

The authors' clinical model uses the novel approach of integrating acupuncture with trigger point injections for patients with fibromyalgia. As trigger point injections and acupuncture have been shown to modulate both the peripheral and central nervous systems, it is possible that the combination of the 2 procedures may have a synergistic effect. It has been the authors' experiences, both in the current case and in other cases, that the combination of the 2 interventions, which use the concepts of acupuncture, provides improved clinical outcomes. This result is noteworthy because fibromyalgia is associated with significant morbidity and limited treatment options. Further research is warranted to examine whether the combination of acupuncture and trigger point injections provides an enhanced clinical benefit in patients with fibromyalgia when compared with either intervention alone.

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## AUTHOR DISCLOSURE STATEMENT

The authors declare no conflicts of interest.

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# Efficacy of Trigger Point Injections in Patients with Lumbar Disc Hernia without Indication for Surgery

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**Study Design:** Prospective comparative study.

**Purpose:** To investigate the efficacy of gluteal trigger point (TP) injections with prilocaine in patients with lumbosacral radiculopathy complaining of gluteal pain.

**Overview of Literature:** TP injections can be performed using several anesthetic agents, primarily lidocaine and prilocaine. While several studies have used lidocaine, few have used prilocaine.

**Methods:** A total of 65 patients who presented at the polyclinic with complaints of lower back pain with lumbar disc herniation (based on physical examination and magnetic resonance imaging) and TPs in the gluteal region were included in this prospective comparative study. Group 1 comprised 30 patients who were given TP injections, a home exercise program, and oral medications, and group 2 comprised 35 patients who were only treated with a home exercise program and oral medications. The patients' demographic data, Oswestry Disability Index (ODI) scores, and Visual Analog Scale (VAS) scores were recorded, and these data were evaluated at 1- and 3-month follow-ups.

**Results:** The ODI and VAS scores of both groups significantly decreased initially and at the follow-up examinations, but the decreases were more marked in group 1.

**Conclusions:** We obtained better results with TP injections than only a home exercise program and oral medications in patients with radiculopathy and TPs in the gluteal region.

**Keywords:** Lumbar disc disease; Trigger point; Injection

## Introduction

Lumbar disc herniation (LDH) is one of the most common causes of nerve root pain and results from the displacement of the nucleus pulposus inside the vertebral canal. It may also manifest as lumbosacral radiculopathy

due to pressure on the spinal nerve roots [1]. This condition presents with dermatomal pain due to compression of the nerve root and weakness and paresis of the muscle groups and can be diagnosed with a positive straight leg raise (Lasègue) test [2]. Several studies have shown that trigger points (TPs) are common in patients with radicu-

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lopathy. The presence of TP-related pain in radiculopathy, in addition to peripheral neuropathy, is a major factor of symptom aggravation [3]. TPs are irritable spots in the skeletal muscle and may manifest as palpable nodules [4]. They are common sources of regional neuromusculoskeletal pain that are widely accepted by clinicians and researchers [5]. Simons et al. [6] defined TPs as painful foci in a taut band in the skeletal muscle. These foci can be active or latent; active TPs cause spontaneous pain and motor symptoms with nerve stimulation, whereas latent TPs do not cause painful symptoms. In addition, active TPs have shown the presence of chemical mediators, such as bradykinin and serotonin [7]. Pharmacological agents, manual and physical therapy, dry needling, TP injection, and botulinum toxin injections have been widely used for the treatment of TP; however, the most important step is treating the main cause of its pathogenesis [8]. TP injections are primarily performed using lidocaine or prilocaine, and while several studies have used lidocaine, few have used prilocaine.

Therefore, we investigated the efficacy of gluteal TP injections using prilocaine in patients with lumbosacral radiculopathy and pain in the gluteal region.

## Materials and Methods

### 1. Subject

The present study initially evaluated data from 275 patients who were diagnosed with LDH based on clinical examination and magnetic resonance imaging (MRI) between November 2013 and March 2014. The study included 65 patients with LDH with or without spinal canal stenosis of 20%–30% on lumbar MRI or TPs associated with canal stenosis. The patients with LDH comprised the main study group, and some of these patients had accompanying spinal stenosis. A problem for patients is that it is nearly impossible to create a specific group excluding spinal stenosis. In addition, some patients have stenosis outside the limits of the accepted stenotic value [3,4]. We expected that spinal stenosis was accompanied by findings of disc and nerve root pressure. Three clinicians in the Department of Neurosurgery evaluated all the patients and their images and reached a consensus on all decisions regarding medical and physical therapy. Patients with concomitant conditions, such as sciatica, piriformis syndrome, previous surgery in the gluteal region, metastatic

carcinoma, or a history of using a prosthesis compromising hip biomechanics, were excluded from the study.

The patients were divided into two groups. Patients in group 1 were given injection therapy, a home exercise program, and oral nonsteroidal anti-inflammatory agents, and those in group 2 received the home exercise program and oral medications only.

In patients given injection therapy, TPs were detected with patients in the prone position using the flat palpation technique in which the taut band and TPs were localized in the superolateral gluteal region and compressed between the thumb and index finger and against the underlying bone and soft tissue [9]. The diagnostic criteria for a TP include the presence of a hypersensitive spot and patient recognition of the elicited pain as it is being felt, the presence of a taut band, and the presence of a local twitch response and jump sign, although the presence of this sign is not required for diagnosis [4]. The presence of two TPs within 3 cm of each other was unacceptable, and the most appropriate spot for the injection was identified as the TP. The presence of a maximum of three TPs in the gluteal region was considered appropriate for injection. After positively identifying a TP, the pain was scored on a Visual Analog Scale (VAS). One TP injection was performed in 30 patients consenting to injection therapy. A sterile 21-gauge needle attached to a 10-mL syringe containing 5 mL of prilocaine and 5 mL of normal saline was used for each patient. With the patient in the prone position, approximately 3 mL of the sterile mixture was injected at the painful TP in the gluteal region using the technique suggested by Simons et al. [6], whereby the syringe is held with the fingers of the dominant hand, the TP is held between the index and middle fingers of the non-dominant hand, and the needle is inserted into the muscle at a 90° angle.

Each patient was also given a home exercise program and an oral nonsteroidal anti-inflammatory agent. Patients were instructed to perform the exercises, which included postural training, muscle reactivation, and correction of flexibility and strength deficits, and the patients progressed to 4–6 weeks of functional exercises. Following recovery, the patients underwent a follow-up exercise program that included protective exercises for 2–3 days a week [10]. Oral medications included a nonsteroidal anti-inflammatory drug (etodolac, 400 mg twice/day), a muscle relaxant (thiocolchicoside, 8 mg twice/day), and an anti-inflammatory gel (ibuprofen gel, 3 times/day for

10 days). Demographic data, Oswestry Disability Index (ODI) scores, and VAS scores were recorded for each patient, and all patients were evaluated 1 and 3 months after instituting these measures.

Pain severity was evaluated on a 10-mm VAS ranging from 0 (no pain) to 10 (the worst pain imaginable). Function was evaluated using the Turkish ODI consisting of 10 items: pain intensity, personal care, lifting, sitting, walking, standing, sleeping, social life, travel, and degree of pain. Greater the total score, greater was the disability. The validity and reliability of the Turkish ODI have been evaluated previously [11].

## 2. Ethics and consent to participate

The study received ethical committee approval from Kanuni Sultan Suleyman Training and Research Hospital Clinical Research Ethics Committee (approval no., KAEK/2/10).

## 3. Statistics

Descriptive statistics are presented as mean, standard deviation, median, minimum, maximum, frequency, and ratio. The Kolmogorov–Smirnov test was used to measure the distribution of variables. Quantitative independent data were analyzed using the independent sample *t*-test

and Mann–Whitney *U*-test, and dependent data were analyzed using the Wilcoxon test. The chi-square test was used to analyze the qualitative independent data. Statistical analyses were performed using IBM SPSS Statistics ver. 22.0 software (IBM Corp., Armonk, NY, USA).

## Results

No significant differences were observed in age, sex, or baseline VAS score between the case and control groups ( $p>0.005$ ) (Table 1). The VAS scores at 1 and 3 months were significantly ( $p<0.05$ ) lower in the case versus the control group and significantly ( $p<0.05$ ) lower than baseline values in both groups (Table 1, Fig. 1). There were no significant differences ( $p>0.005$ ) in baseline ODI scores between groups, and the ODI scores at 1 and 3 months were significantly ( $p<0.05$ ) lower in the case than control groups and significantly ( $p<0.05$ ) lower than the baseline values in both groups (Table 1, Fig. 2).

## Discussion

Low back pain (LBP) is a common problem that is treated by both primary care and specialty physicians. While its etiology includes several factors, LBP is usually associated with muscular components. Identifying the cause of LBP

**Table 1.** Comparison of the pre- and post-injection VAS and ODI scores of the two groups

Variable	Case group			Control group			<i>p</i> -value
	Value	Median	<i>p</i> -value <sup>a)</sup>	Value	Median	<i>p</i> -value <sup>a)</sup>	
Age (yr)	44.5±9.9	45.0		46.2±11.0	45.0		0.533 <sup>b)</sup>
Sex							0.104 <sup>c)</sup>
Female	27 (90.0)			26 (74.3)			
Male	3 (10.0)			9 (25.7)			
VAS							
Baseline	8.4±0.5	8.0		8.2±0.4	8.0		0.138 <sup>d)</sup>
Month 1	2.9±1.4	2.0	<b>0.000<sup>e)</sup></b>	6.7±1.4	7.0	<b>0.000<sup>e)</sup></b>	<b>0.000<sup>d)</sup></b>
Month 3	2.9±1.4	2.0	<b>0.000<sup>e)</sup></b>	6.7±1.4	7.0	<b>0.000<sup>e)</sup></b>	<b>0.000<sup>d)</sup></b>
ODI							
Baseline	84.6±8.3	90.0		88.2±3.8	90.0		0.091 <sup>d)</sup>
Month 1	40.2±17.8	38.0	<b>0.000<sup>e)</sup></b>	78.3±7.5	80.0	<b>0.000<sup>e)</sup></b>	<b>0.000<sup>d)</sup></b>
Month 3	40.9±17.8	40.0	<b>0.000<sup>e)</sup></b>	80.0±0.0	80.0	<b>0.000<sup>e)</sup></b>	<b>0.000<sup>d)</sup></b>

Values are presented as mean±standard deviation or number (%), unless otherwise stated. Significant statistically values were written in bold type. VAS, Visual Analog Scale; ODI, Oswestry Disability Index.

<sup>a)</sup>By comparison with baseline in the groups. <sup>b)</sup>By *t*-test. <sup>c)</sup>By chi-square test. <sup>d)</sup>By Mann-Whitney *U*-test. <sup>e)</sup>By Wilcoxon test.

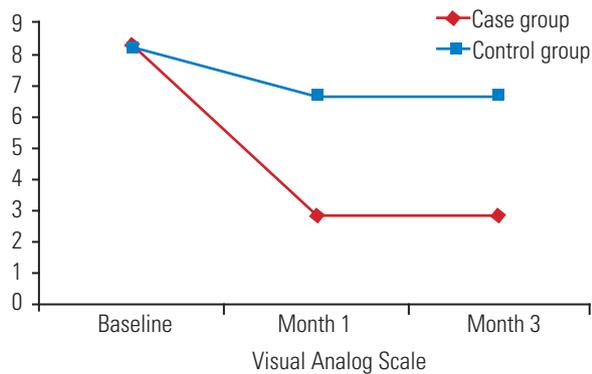


Fig. 1. Visual Analog Scale scores of the two groups.

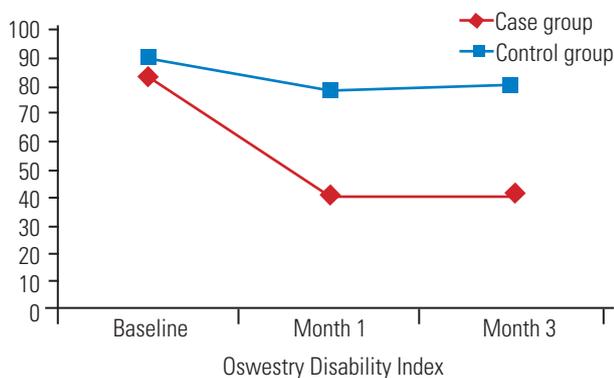


Fig. 2. Oswestry Disability Index scores of the two groups.

in clinical practice is challenging because there are usually several causes. Intervertebral disc herniation, one of the most common causes of LBP, affects the nerve roots, leading to lumbosacral radiculopathy [12], which is often accompanied by lumbar and gluteal local TPs. Patients with TPs experience additional pain and discomfort, which can complicate radiculopathy treatment [13].

In a study of 207 patients with gluteal TPs, Adelmanesh et al. [12] found that 74.6% had TPs ipsilateral to the radiculopathy. Active TPs located in the gluteus minimus muscle can mimic sciatica during the chronic phase of radiculopathy [12]. The location of the TPs is often not anatomically clear. Nevertheless, Akamatsu et al. [14] identified TPs as entry points of the spinal accessory nerve into the trapezius muscle and tendon in a cadaver study. TPs may result from trauma to or overload of specific muscle groups. Repetitive strain injuries can cause the formation of chronic TPs. Instead of the generic term “muscle pain,” terms such as local soft tissue pain, local fibromyalgia, and idiopathic myalgia may be used. TPs can be palpated as taut bands in specific locations [15]; the palpation of

these tender spots causes a local twitch response, which activates alpha motor neurons. In our study, a local twitch response was obtained at the active TP foci. A detailed history and physical examination are essential for the diagnosis of a TP due to limited diagnostic laboratory tests [16].

Iglesias-González et al. [17] evaluated 42 patients with nonspecific LBP and revealed that TPs in the lumbar area and hip muscles are particularly important sources of nonspecific LBP. They also demonstrated that patients with nonspecific LBP have a greater disability and worse sleep quality than individuals without a TP [17]. TP injection is preferred when conservative methods fail [9]. Various conservative approaches can be used in the management of TP, the most common of which are dry needling and local anesthetic administration. The gauge of the needle used for TP injection can also affect treatment success. While previous studies used 21-, 25-, and 27-gauge needles [18], we preferred to use a green 21-gauge needle in the present study.

The injection site should be cleaned with an antiseptic agent and sterilized prior to performing the injection [19]. We used Betadine to clean the site, with the patient in a prone position, using the technique of Simons et al. [6] for the injection, which we believed to be more effective [20]. *In vitro* studies have revealed that local anesthetics reduce the release of free oxygen radicals from polymorphonuclear leukocytes (PMNLs) [21]. *In vivo* studies have shown that local anesthetic administration inhibits adhesion and leukocyte migration [22,23]. Local anesthetics have also been found to decrease the release of histamine from mast cells and leukotriene B4 from PMNLs as well as the release of interleukin-1 (IL-1) [24]. Due to their short half-lives and lower local irritant effects, lidocaine and prilocaine are the most commonly used local anesthetics for injection [9]. Hameroff et al. [25] administered bupivacaine 0.5%, etidocaine 1%, or physiologic saline to the neck and lumbar muscles and observed a greater pain decrease with the use of local anesthetics compared with saline, although no difference was noted between the two anesthetics. Frost [26] treated patients with acute lumbar pain with either mepivacaine or saline and observed no difference after 2 weeks.

In the present study, patients undergoing medical therapy and an exercise program comprised the control group. The group receiving TP injections had significantly reduced pain and improved functional status compared

with the controls. The different results obtained by various studies may be due to the differences in the gauge of the needle or active ingredient used as well as the method of application. Any failure to precisely localize the TP and injection of a spot adjacent to the TP may also yield unsatisfactory results. We believe that the mechanism of action and features of the anesthetic are also important determinants of TP injection success. Yuan et al. [27] showed that lidocaine inhibits lipopolysaccharide-related inflammatory mediator release from microglia and reported that the mechanism of action involves the blockage of the p38 mitogen-activated protein kinase and nuclear factor-kappa B signaling pathways. Lidocaine has anti-inflammatory effects on monocytes, macrophages, and neutrophils as well as on LPS, thereby inhibiting nitric oxide, prostaglandin E2, tumor necrosis factor- $\alpha$ , IL-1 $\beta$ , and monocyte chemoattractant protein-1 [28]. Given that molecules such as IL-1 are often present in the vicinity of TPs, lidocaine reduces the secondary pain due to the TP via both neurological and biochemical mechanisms. The effectiveness of various procedures, such as injections in the epidural space, facet joints, and locally sensitive TPs as well as nerve blocks, has been discussed in large database collection trials that question the efficacy of injection therapy in patients with posterior back pain [29]. Statements on the efficacy of multiple injections and various nerve blocks in the literature compared with such nonspecific studies have shown high heterogeneity [19,25].

Although few studies have used prilocaine, we prefer its use for TP injection. We found that it was effective for the treatment of TPs, and its mechanism of action may be similar to the biochemical processes involving lidocaine. Further molecular studies on the exact biochemical mechanisms of prilocaine are warranted.

## Conclusions

Our study showed that patients with radiculopathy, which was possibly due to secondary TPs in the gluteal region, have favorable results with TP injection. We suggest that TP injection be part of the treatment of lumbosacral radiculopathy in selected patients.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Article: Point injection for treating nephritic colic in 101 cases.  
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and blood. Therefore, the three points are used together as the main points. Fenglong (ST 40) should be added to resolve phlegm, Yanglingquan (GB 34) added to dredge the channels and collaterals. When the main and auxiliary points are used together, they can stop pain by removing the

Moreover, the She Xiang (麝香 Moschus), Tan Xiang (檀香 Lignum Santali), Su He Xiang (苏合香 Styrax Liquidus) and Jiang Xiang (降香 Lignum Dalbergiae Odoriferae) contained in the catgut suture may strengthen the actions of expelling the turbid, and promoting flow of *qi* and blood so as to

interior obstruction. It may take about 2 weeks for absorption of the catgut suture embedded, during which time, while the catgut suture is being absorbed, the points are being constantly stimulated.

remove stasis and stop pain.

(Chen Zhengqiu 陈正秋)

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## Point Injection for Treating Nephritic Colic in 101 Cases

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Since 1994, the authors have treated 101 cases of nephritic colic by point injection therapy and achieved good curative results. Of them, 70 cases were diagnosed as having renal or ureteral calculi confirmed by abdominal X-ray and B- ultrasonic examination; and the others had the following symptoms: 1) sudden onset; 2) colic in unilateral lumbar and abdominal regions; 3) percussion-induced pain in the ipsilateral kidney region; and 4) erythrocytes or visible blood in urine.

Therapeutic methods: The patient was in the position of lateral recumbent with the affected side facing upward. Three tender points were detected by pressing with the operator's thumb in the regions respectively corresponding to Shenshu (BL 23) located at 1.5 *cuo* lateral to the locus between L<sub>2</sub> and L<sub>3</sub>, Qihaihu (BL 24) located at 1.5 *cuo* lateral to the locus between L<sub>3</sub> and L<sub>4</sub>, and Zhishi (BL 52) located at 3 *cuo* lateral to the locus between L<sub>2</sub> and L<sub>3</sub>. After conventional sterilization, 3-5 ml of lidocaine (1%) was injected into the above three points.

Criteria for the therapeutic effects: 1) Cured: Disappearance of the colic. 2) Improved: Alleviation of the colic, with supporting treatment of antispastics like atropine. 3) Failed: No improvement, with dependence on of analgetics and antispastics such as dolantin.

Of the 101 cases treated, 82 cases (81.2%) were cured, 12 cases (11.9%) improved, and 7 cases (6.9%) failed.

According to authors experience, 1) the tender points should be detected accurately; 2) the needle insertion should be pointed to the tip of the processus transverses of the corresponding lumbar vertebra, the insertion depth should be of the same level as the tip of the processus transverse, and the needle should be slowly withdrawn while injecting the drug. In some cases, alleviation of colic was felt before complete withdrawal of the needle, showing a rapid efficacy. This therapy is easy to operate and safe without side-effects, being a good approach to treating the disease in clinics.

(Translated by Chen Zhengqiu 陈正秋)

**Format:** Abstract

Altern Ther Health Med. 2018 Jan;24(1):56-60.

## **Dextrose Prolotherapy for Chronic Shoulder Pain: A Case Report.**

Seenauth C, Inouye V, Langland JO.

### **Abstract**

**Context** • Shoulder pain is one of the most common pain complaints reported by patients. Consensus is lacking on its ideal treatment, and many different treatments are available and used. Prolotherapy is an injection-based therapy that has shown significant results in treating many common musculoskeletal pain conditions, including osteoarthritis, lateral epicondylitis, and low-back pain. **Objective** • The study intended to evaluate the use of dextrose prolotherapy in the treatment of shoulder pain. **Design** • The research team performed a case study. **Setting** • The study occurred at the Medical Center at Southwest College of Naturopathic Medicine (Tempe, AZ, USA). **Participant** • The participant was a middle-aged male with a long-term history of untreated shoulder pain. **Intervention** • Injections were placed in the patient's glenohumeral joint space, the acromioclavicular joint, the subacromial space, and the insertion of the supraspinatus. **Each location was injected with a solution of 50% dextrose diluted with 1% lidocaine, 0.25% bupivacaine, and 1 mg methylcobalamin.** The final concentration of dextrose in the solution was approximately 22.8%. **Outcome Measures** • The patient completed questionnaires (numerical rating scale, verbally reported at the beginning of each visit) indicating his level of pain on a scale of 0 to 10, with 0 = no pain and 10 = worst pain. **Results** • Following 3 sessions of prolotherapy, the **patient reported a 90% reduction in pain and full restoration of normal activity.** **Conclusions** • The findings suggest that dextrose prolotherapy may be an effective treatment for chronic shoulder pain and may be an alternative to surgery or other more costly and invasive interventions.

PMID: 29101774

## Therapeutic Effects of the Point-injection Therapy on Primary Trigeminal Neuralgia — An Observation of 103 Cases

Lin Mao 林 矛

Maoming Municipal Hospital of Traditional Chinese Medicine, Maoming 525000, Guangdong Province

From 1996 to 1999, the author treated 103 cases of primary trigeminal neuralgia by point-injection with lidocaine, VB<sub>1</sub> and VB<sub>12</sub>, and obtained quite good therapeutic results. A report follows.

### General Data

In this series of 103 cases of primary trigeminal neuralgia, 45 cases were male and 58 female, ranging in age from 21 to 69 years, and in duration of the illness from 1 month to 21 years.

These cases were characterized by sudden severe pain in the trigeminal nerve distributing area of the face. It would happen once a day in the mild cases, or several dozen times a day in the severe cases.

### Methods of Treatment

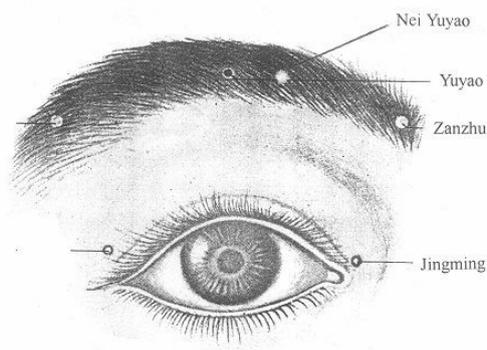
1. For neuralgia of the 1st branch, Nei Yuyao (内鱼腰 Extra) was selected. A No. 5 syringe needle was inserted into the point 0.5 cm deep to reach the bone surface of the orbital margin and induce a sensation of electric transmission with no blood let out, when 1ml of 2% lidocaine was injected into the point. 5-minute later, when the pain in the 1st branch area was alleviated or disappeared, the injection of 50mg VB<sub>1</sub> and 0.25mg VB<sub>12</sub> was followed.

2. For the neuralgia of the 2nd branch, Sibai (ST 2) was selected. A No.5 syringe needle was inserted into the point via the infraorbital foramen of an angle of 40°-50° posterolaterally upwards to a depth limited within 1cm, followed by injection of the medicines upon appearance of the electric shock sensation, with the same quantity and method as

mentioned above.

3. For neuralgia of the 3rd branch, Xiaguan (ST 7) was selected. A No. 5 long dental syringe needle was inserted into the point posteriorly towards the medial side for about 4 cm (never deeper than 5cm). When the sensation like a electric shock radiated to the mandibula, 2ml of 2% lidocaine was injected into the point slowly. 5 minutes later, when the pain in the 3rd branch was alleviated or disappeared, the injection of 100mg VB<sub>1</sub> and 0.5mg VB<sub>12</sub> was followed.

The treatment was given once daily, 10 sessions constituting one therapeutic course, with a 3-day interval between courses.



### Criteria for Therapeutic Effects

Cured: Complete disappearance of the pain, with no recurrence in a period of 3 months. Markedly effective: Disappearance of the pain, but with mild recurrence 3 months after treatment. Improved: Alleviation of the pain, with reduced frequency of

the episodes. Ineffective: No obvious improvement after the treatment.

### **Results of Treatment**

After 1-3 courses of treatment, the patients were followed up for 3 months. Among the 103 cases treated, 56 cases (54.37%) were cured, 29 cases (28.16%) markedly effective, 16 cases (15.53%) improved, and 2 cases (1.94%) ineffective. The total effective rate was 98.06%.

### **Illustrative Case**

Mr. Feng, aged 55 years, paid his first visit on May 13, 1998. Two months before, the patient got sudden severe pain on the right side of the face, with intermittent episodes from several times to several dozen times a day and each attack lasting 10-60 seconds. He had been treated with some medicines but with no effect. The diagnosis was right trigeminal neuralgia of the 3rd branch. The

point-injection at Xiaguan (ST 7) with lidocaine, VB<sub>1</sub> and VB<sub>12</sub> was given once daily. After 6 treatments, the pain disappeared. Another 4 treatments were then given for consolidation. No recurrence was found in a 3-month follow-up period.

### **Comment**

By means of facial point-injection, the author has obtained quite good therapeutic results in the treatment of primary trigeminal neuralgia. The points respectively selected are Nei Yuyao (EX-HN4) for neuralgia of the 1st branch, Sibai (ST 2) for the 2nd branch, and Xiaguan (ST 7) for the 3rd branch. Good therapeutic effects can be expected only when the needling sensation is made to radiate to the painful area. This therapy has proved highly effective for primary trigeminal neuralgia.

(Translated by Wang Xinzong 王新中)

## 16 CASES OF SCALENUS SYNDROME TREATED BY MASSAGE AND ACUPOINT-INJECTION

Peng Junyu 彭浚宇

*Wuhu Municipal Hospital of Traditional Chinese Medicine, Anhui Province 241000*

Scalenus syndrome is a kind of thoracic outlet syndrome. I treated 16 such cases with massage in combination with acupoint injection from 1989-1996. The results were satisfactory and introduced as follows.

### Clinical Data

In this series, all the 16 cases were female, 24-40 years old, with a duration of illness from 3 months to 4 years (mean, 14 months). All of them had a history of traumatic injury of the shoulder, or continual backward extension of the neck, stretching the hand over the head, and hyperabduction of the upper arm in doing their jobs. They all had symptoms and signs like pain and numbness in the shoulder, arm, hand, grasp weakness, fullness in the infraclavicular fossa, hypertrophy of scalene muscle and positive vascular Adson sign.<sup>1</sup> 12 cases got coldness of the affected limb and prolonged filling time of the capillaries; 9 cases got uncoordinated fine movements of the fingers; and 4 cases thenal muscular atrophy. X-ray findings were all normal except one showing lengthened 7th cervical transverse process.

### Method of Treatment

1. Massage therapy: The patient was asked to take sitting position, with the head upright and neck muscle relaxed. The operator stood at the affected side of the patient, holding the affected arm in his left hand. Kneading and rolling manipulations were first applied at the shoulder and medial side of the upper arm (mainly on the distending and tender spots) for 3-5 min. Then, manipulations of kneading-pressing on acupoints Tianzhen (SI 9), Jianyu (LI 15), and Jianjing (GB 21) with the thumb, forceful pressing-grasping with the thumb, the index and middle finger on Tianzong (SI 11), Quchi (LI 11), Shousanli (LI 10), and Hegu (LI 4), and then flicking-poking and lifting-pinching on Quepen (St 12) and Jingbi (Extra 13) were performed, meanwhile the affected shoulder was continuously and slowly lifted and abducted by the operator's left hand for about 5 minutes. In the end, the affected limb was shaken for dozens of times, followed by repeated rubbing with palm along the most distending and sore parts of the scalene muscles till the skin became warm and turned slightly red. The above manipulations

were performed once a day.

2. Acupoint-injection: A mixture of 2 ml of 1% procaine hydrochloride and 100 µg of Vit.B<sub>12</sub> was slowly injected with a sterilized No.5 syringe needle into the acupoint Jingbi (Extra 13) after the needle was perpendicularly inserted into the skin and then advanced horizontally for about 1 cm until a needling sensation was experienced.<sup>2</sup> The injection was given once every five days, and infra-red radiation was supplemented after the injection.

### **Therapeutic Result**

15 cases got cure. Only 1 case complicated with lengthened 7th cervical transverse process still got pain and numbness of the upper arm and grasp weakness upon ill position of the affected arm, although she had got her condition improved with negative Adson sign.

### **Experience**

The triangle between the scalene muscles is a narrow space at the thoracic outlet through which the brachial plexus nerve trunks and axillary vessels pass. Inflammation, trauma or irritation will cause spasm and edema of the local tissues and compression of the brachial plexus trunks and axillary vessels in this narrower space, leading to appearance of the symptoms and signs. Moreover, the compression and irritation of the brachial plexus trunks may, in turn, increase spasm of the scalene muscles, resulting in a vicious circle. Therefore, relieving spasm and eliminating swelling should be the principle of treatment for this condition. In this study,

massage and point-injection are used to prevent this vicious circle of irritation-spasm-irritation of the muscular tissues by means of relaxing the spasmodic muscles to promote blood circulation and relieve pain by removing stagnation and obstruction in the channels. Kneading, rolling, and rubbing manipulations should be mild, gentle and rhythmic at first in order not to cause new injuries of the scalene muscles but to promote circulation and accelerate absorption of inflammatory exudate and lower down the local sensitiveness to the pain. Then, forceful pinching-grasping along the course of the affected channels is supplemented to promote circulation of *qi* and blood, and relax the muscles and tendons by means of conduction of the channels and collaterals. At last, flicking-poking and shaking manipulations are applied to relax local adhesion. Point Jingbi (Extra 13) is mainly indicated for numbness, weakness and myoatrophy of the upper limbs. The injection should not be made too deep lest the apex of the lung and vessels in the deeper part would be injured. No special handling is necessary for some patients who may get aggravated pain after the injection, for it may disappear spontaneously within one or two days.

This comprehensive treatment should be carried on perseveringly, and the relief of symptoms generally requires 1-2 courses of treatment, i.e. 20-40 days. The patients should be advised to do suspension exercise of the muscles, correct shoulder drops, avoid stretching hand over the head, heavy-lifting, upward lifting and hyperabduction of the upper arm, especially during sleep.

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(Translated by Wang Xinzhong)

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**Exhibit I Evidence for Substance Use Disorder**

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# Acupuncture: A Key Solution for Treating America's Painkiller Epidemic

## THE U.S. PAIN EPIDEMIC



**4x**

Sales of Prescription Opioids Have Quadrupled Since 1999



**17,000**

Prescription Opioid Deaths Annually



**80,000**

NSAID and Acetaminophen Related ER Visits Annually



**\$635 Billion**

Annual Economic Cost of Chronic Pain\*  
\*Additional Health Care Costs and Lost Productivity

*According to the Joint Commission on January 1, 2015, both pharmacologic and non-pharmacologic strategies such as acupuncture therapy have a role in the management of pain.*

## TRY ACUPUNCTURE before PILLS

### REDUCE COSTS

### IMPROVE OUTCOMES

### INCREASE SATISFACTION

## REDUCE COSTS

- 1** Lower Cost to Insurance Companies
- 2** Reduced Average Out-of-Pocket Expenses

- 3** Patients Avoid Expensive / Risky Procedures
- 4** Fewer Inpatient Expenses

## IMPROVE OUTCOMES & SATISFACTION



### Non-Addictive

Acupuncture is a useful adjunctive therapy in the treatment of opiate and other addictions, but itself is non-addictive.



### Happier Patients

Acupuncture is patient-centered, safe, effective, and well received in the clinic.



### Low Cost

Insurance policies that cover acupuncture only cost an extra \$0.37-0.76 per person each month.



### Evidence Based

Research shows patients who receive acupuncture have more relief from pain than those who did not receive acupuncture.

*Acupuncture is Safe, Proven, Effective & Non-Addictive.*

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# **Acupuncture's Role in Solving the Opioid Epidemic:**

## **Evidence, Cost-Effectiveness, and Care Availability for Acupuncture as a Primary, Non-Pharmacologic Method for Pain Relief and Management**

**White Paper 2017**

**The American Society of Acupuncturists (ASA)  
The American Alliance for Professional Acupuncture Safety (AAPAS)  
The Acupuncture Now Foundation (ANF)  
The American TCM Association (ATCMA)  
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**Acupuncture's Role in Solving the Opioid Epidemic:  
Evidence, Cost-Effectiveness, and Care Availability for Acupuncture  
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**Abstract**

The United States is facing a national opioid epidemic, and medical systems are in need of non-pharmacologic strategies that can be employed to decrease the public's opioid dependence. Acupuncture has emerged as a powerful, evidence-based, safe, cost-effective, and available treatment modality suitable to meeting this need. Acupuncture has been shown to be effective for the management of numerous types of pain, and mechanisms of action for acupuncture have been described and are understandable from biomedical, physiologic perspectives. Further, acupuncture's cost-effectiveness could dramatically decrease health care expenditures, both from the standpoint of treating acute pain and through avoiding the development of opioid addiction that requires costly care, destroys quality of life, and can lead to fatal overdose. Numerous federal regulatory agencies have advised or mandated that healthcare systems and providers offer non-pharmacologic treatment options, and acupuncture stands as the most evidence-based, immediately available choice to fulfil these calls. Acupuncture can safely, easily, and cost-effectively be incorporated into hospital settings as diverse as the emergency department, labor and delivery suites, and neonatal intensive care units to treat a variety of pain seen commonly in hospitals. Acupuncture is already being successfully and meaningfully utilized by the Veterans Administration and various branches of the U.S. Military.

**1. Acupuncture is an effective, safe, and cost-effective treatment for numerous types of acute and chronic pain. Acupuncture should be recommended as a first line treatment for pain before opiates are prescribed, and may reduce opioid use.**

**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 numerous types of pain, especially chronic pain, as well as the use of acupuncture for a diverse array of conditions (Table 1<sup>1</sup>, Appendix 1). Acupuncture has been shown to be effective for treating various types of pain, with the strongest evidence emerging for **back pain, neck pain, shoulder pain, chronic headache, and osteoarthritis**. 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 standard deviation (SD), 95% confidence interval (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. 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 ( $p < 0.001$ ).<sup>2</sup>

<b>Table 1. Acupuncture for the use of numerous conditions including pain conditions.</b>	
<b>The Acupuncture Evidence Project</b>	
<b>(Mar 2013 - Sept 2016)</b>	
<b>Evidence of positive effect</b>	
<ul style="list-style-type: none"> <li>● Allergic rhinitis (perennial &amp; seasonal)</li> <li>● Chemotherapy-induced nausea and vomiting (CINV) (with anti-emetics)</li> <li>● Chronic low back pain</li> <li>● Headache (tension-type and chronic)</li> <li>● Knee osteoarthritis</li> <li>● Migraine prophylaxis</li> <li>● Post-operative nausea &amp; vomiting</li> <li>● Post-operative pain</li> </ul>	
<b>Evidence of potential positive effect</b>	
<ul style="list-style-type: none"> <li>● Acute low back pain</li> <li>● Acute stroke</li> <li>● Ambulatory anaesthesia</li> <li>● Anxiety</li> <li>● Aromatase-inhibitor-induced arthralgia</li> <li>● Asthma in adults</li> <li>● Back or pelvic pain during pregnancy</li> <li>● Cancer pain</li> <li>● Cancer-related fatigue</li> <li>● Constipation</li> <li>● Craniotomy anaesthesia</li> <li>● Depression (with antidepressants)</li> <li>● Dry eye</li> <li>● Hypertension (with medication)</li> <li>● Insomnia</li> <li>● Irritable bowel syndrome</li> <li>● Labor pain</li> <li>● Lateral elbow pain</li> <li>● Menopausal hot flashes</li> </ul>	<ul style="list-style-type: none"> <li>● Modulating sensory perception thresholds</li> <li>● Neck pain (some types/non-whiplash)</li> <li>● Obesity</li> <li>● Peri-menopausal &amp; post-menopausal insomnia</li> <li>● Plantar heel pain</li> <li>● Post-stroke insomnia</li> <li>● Post-stroke shoulder pain</li> <li>● Post-stroke spasticity</li> <li>● Post-traumatic stress disorder</li> <li>● Prostatitis pain/chronic pelvic pain syndrome</li> <li>● Recovery after colorectal cancer resection</li> <li>● Restless leg syndrome</li> <li>● Schizophrenia (with antipsychotics)</li> <li>● Sciatica</li> <li>● Shoulder impingement syndrome (early stage) (with exercise)</li> <li>● Shoulder pain</li> <li>● Smoking cessation (up to 3 months)</li> <li>● Stroke rehabilitation</li> <li>● Temporomandibular joint disorder</li> </ul>

In the largest study of its kind 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.<sup>3</sup>

In a network meta-analysis comparing different physical interventions for pain from 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 more significantly effective than muscle-strengthening exercises, standardised mean difference (SMD) = 0.49, 95% CI [0.00-0.98].<sup>4</sup>

In early 2017, the American College of Physicians (ACP) published guidelines based on the evidence for the non-invasive treatment of low back pain. For acute or subacute low back pain, the ACP strongly recommends non-pharmacologic treatment with **acupuncture**, along with superficial heat, massage, or spinal manipulation, and nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants. For chronic low back pain, the ACP also strongly recommends **acupuncture**, in addition to exercise, multidisciplinary rehabilitation, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, and spinal manipulation, etc.<sup>5</sup>

A systematic review and meta-analysis on acupuncture for the treatment of **sciatica** concluded that acupuncture was superior to standard pharmaceutical care (such as ibuprofen, diclofenac, and prednisone) in reducing pain intensity (mean difference (MD) = 1.25, 95% CI [1.63-0.86]) and pain threshold (MD = 1.08, 95% CI [0.98–1.17]).<sup>6</sup>

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 and opioid medications.<sup>7</sup>

A systematic review on acupuncture and moxibustion for **lateral elbow pain** found that acupuncture and moxibustion were superior or equal to standard care.<sup>8</sup>

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, and dexamethasone.<sup>9</sup>

The use of acupuncture to relieve **pain associated with surgical procedures** captured the world's attention in the early 1970's when well-known *New York Times* journalist James Reston, who, while in China, witnessed acupuncture's effectiveness on his post-operative pain, published his personal experience with acupuncture shortly before President Richard Nixon's trip to China. 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.<sup>10,11,12,13,14,15,16,17,18</sup> It is noteworthy that acupuncture has been reported to be effective in pain relief during and after surgical procedures on children and animals as well.<sup>19,20,21,22</sup>

Nonetheless, over the past two decades post-operative pain management has come to rely increasingly on opioids while underutilizing alternative analgesics such as acupuncture. In 2012, surgeons and dentists combined prescribed 16.2% of all opioids in the U.S, trailing only family practices as the leading source of opioid prescriptions at 18.2%.<sup>23</sup> Eighty to ninety-four percent of patients undergoing low risk surgical procedures fill a prescription for opioids within 7 days.<sup>24,25</sup> Recent data has shown that opioid prescriptions vary widely and that the majority of surgical patients are over-prescribed opioids, as approximately 70% of pills go unused.<sup>26</sup> The risk of chronic

opioid use after surgery in previously non-dependent patients is determined to be 5.9 – 6.5%,<sup>27</sup> although in select populations such as head and neck cancer patients, the risk is up to 40%.<sup>28</sup> The increase in post-operative opioid use is somewhat paradoxical considering that known adverse effects such as sedation, pneumonia,<sup>29,30</sup> ileus, urinary retention, and delirium prolong patient recovery and delay the meeting of discharge goals.<sup>31</sup>

Acupuncture is a promising adjunctive analgesic modality to reduce the risk of post-operative opioid dependence. A meta-analysis published in late 2017 in the *Journal of the American Medical Association (JAMA Surgery)* focused on non-pharmacological treatments in reducing pain after total knee arthroplasty. Thirty-nine randomized clinical trials were included in the meta-analysis (2,391 patients). Moderate-certainty level evidence showed that electrotherapy reduced the use of opioids (MD = 3.50, 95% CI [5.90-1.10]) morphine equivalents in milligrams per kilogram per 48 hours ( $p = .004$ ,  $I^2 = 17\%$ ), and that acupuncture delayed opioid use (MD = 46.17, 95% CI [20.84-71.50]) minutes to the first patient-controlled analgesia ( $p < .001$ ,  $I^2 = 19\%$ ). There was low-certainty level evidence that acupuncture improved pain (MD = 1.14, 95% CI [1.90-0.38] on a visual analog scale at 2 days ( $p = .003$ ,  $I^2 = 0\%$ ). Evidence showed that acupuncture is better than cryotherapy, continuous passive motion, and preoperative exercise in the studied condition.<sup>32</sup> Reduction in opioid use has been demonstrated across a wide range of both minor and major surgical procedures, including cardiac surgery,<sup>33</sup> thoracic surgery,<sup>34</sup> and craniotomy.<sup>35,36</sup> Moreover, acupuncture may even reduce post-operative ileus and expedite bowel recovery after colorectal cancer resection.<sup>37</sup> As acupuncture is often combined with electric stimulation, electro-acupuncture may have more clinical benefit in post-operative pain management.

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.<sup>38</sup> 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.<sup>39,40,41,42,43</sup>

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. While some studies reported no reduction in analgesic medications, some studies reported reduction of pain during labor, reduced use of opioid medications and epidural analgesia, and a shorter second stage of labor.<sup>44,45,46</sup>

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.<sup>47</sup>

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, electro-acupuncture is probably better than manual acupuncture for pain in fibromyalgia, although more studies are warranted.<sup>48</sup>

A prospective, randomized trial of acupuncture vs. morphine to treat **emergency department/emergency room patients with acute onset, moderate to severe pain** was conducted. Acupuncture provided more effective and faster analgesia than morphine, and was better tolerated. The study included 300 patients, with 150 patients in each group. Success rate was

significantly different between the 2 groups (92% in the acupuncture group vs 78% in the morphine group,  $p < .001$ ). Resolution time was  $16 \pm 8$  minutes in the acupuncture group vs  $28 \pm 14$  minutes in the morphine group ( $p < .005$ ). Overall, 89 patients (29.6%) experienced minor adverse effects; of these, 85 (56.6%) were in the morphine group and only 4 (2.6%) were in the acupuncture group ( $p < .001$ ).<sup>49</sup>

The above mentioned meta-analysis included 29 trials and 17,922 patients with chronic pain conditions; data on longer term follow-up (available for 20 trials, including 6376 patients) suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months after the course of treatment. Patients can generally be reassured that treatment effects persist at least 12 months.<sup>50</sup>

## **1.2 Safety and feasibility 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.<sup>51</sup> In a prospective feasibility study, acupuncture was seen as feasible, safe, and acceptable in an ICU setting by patients from diverse backgrounds.<sup>52</sup> A systematic review suggests that acupuncture performed by trained practitioners using clean needle technique is a generally safe procedure.<sup>53</sup> The medical literature also indicates that acupuncture may be used successfully on cancer patients for symptom management due to the low risks associated with its use.<sup>54</sup>

## **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.<sup>55</sup> In a cost-effectiveness analysis of non-pharmacological treatments for osteoarthritis of the knee, acupuncture was found to be the most cost-effective option when analysis was limited to high-quality studies.<sup>56</sup> Using acupuncture for pain management, patients and insurers can save money and successfully manage their pain and other symptoms without the adverse risks associated with prescription medications. A recent study found that full insurance coverage for acupuncture would increase an average insured member’s monthly health insurance premium from \$0.38 to \$0.76. Acupuncture was noted to save \$35,480, \$32,000, \$9,000, and \$4,246 per patient for migraine, angina pectoris, severe osteoarthritis, and carpal tunnel syndrome respectively.<sup>57</sup> Considering the large fees associated with prescription medications and surgery for pain conditions, acupuncture is extremely cost-effective.

The Acupuncture Evidence Project also enumerates those conditions for which acupuncture has been found to be cost-effective (Table 2).<sup>58</sup>

**Table 2. Conditions with demonstrated evidence of cost effectiveness.**

- Allergic rhinitis
- Low back pain
- Ambulatory anaesthesia
- Migraine
- Chronic pain: neck pain (plus usual medical care)
- Depression
- Osteoarthritis
- Dysmenorrhoea
- Post-operative nausea and vomiting
- Headache

#### **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.<sup>59,60</sup> A pilot RCT also showed a reduction by 39% in OLM use in non-malignant pain after acupuncture, an effect which lasted fewer than 8 weeks after acupuncture treatment ceased.<sup>61</sup> The above mentioned meta-analysis, having moderate-certainty level evidence, showed that electro-acupuncture therapy reduced the use of opioids, and acupuncture delayed opioid use; with low-certainty level evidence indicating that acupuncture improved pain.<sup>62</sup> The conclusions suggest that electro-acupuncture may be effective in reducing or delaying the use of opioid medications.

In a study looking at acupuncture's effectiveness in treating pain in a military cohort at a United States Air Force medical center, acupuncture dramatically decreased the use of opiates and other pain medications among personnel. Opioid prescriptions decreased by 45%, muscle relaxants by 34%, NSAIDs by 42%, and benzodiazepines by 14%. Quality of life measures also showed impressive changes, with some measures of improvements showing statistical significance ( $p < 0.001$ ).<sup>63</sup>

The Veterans Administration is increasingly looking to incorporate acupuncture into care, as is the U.S. Air Force and other branches. Training of military physicians is increasing, and systems are being studied to further incorporate acupuncture. The military is rapidly incorporating this care into its offered services for service members.<sup>64,65</sup>

Studies of the effects of opioid analgesia in the elderly reveal a significant burden of disease due to falls from mental impairment. This is worsened when seniors are using multiple medications affecting cognition. In a recent study from the Journal of the American Geriatric Society, serious falls as per Medicare Part A and B ICD/CPT codes were evaluated in 5,556 nursing home residents aged 65 or greater. Seniors taking  $> 3$  + CNS standardized daily doses were more likely to have a serious fall than those not taking any CNS medications (adjusted odds ratio = 1.83, 95% CI [1.35-2.48]), and the authors urge, "Clinicians should be vigilant for opportunities to discontinue or decrease the doses of individual CNS medications and/or consider non-pharmacological alternatives."<sup>66</sup>

A recent study in the New Zealand Medical Journal noted that medication related harms were both common and created a substantial burden of disease for patients and the healthcare system. They listed opioids first among the six categories of medications causing the most significant burden.<sup>67</sup> In light of the findings of these studies and similar, utilization of non-pharmacologic treatment options such as acupuncture must be a priority of paramount status.

**2. Acupuncture's analgesic mechanisms have been extensively researched and acupuncture can increase the production and release of endogenous opioids in animals and humans.**

Mechanisms underlying acupuncture's analgesic effects have been extensively researched for over 60 years. In animal models, acupuncture and/or electro-acupuncture has been shown to be effective for the alleviation of inflammatory, neuropathic, cancer-related, and visceral pain. Mechano-transduction of the needling stimulus at specific points on the body triggers the release of ATP and adenosine, which bind to local afferents.<sup>68,69</sup> Ascending neural pathways involving A $\beta$ , A $\delta$ , and C sensory fibres have been mapped, as well as a mesolimbic analgesic loop in the brain and brainstem, descending pathway mechanisms, dopaminergic contributors, and cytokine, glutamate, nitric oxide, and gamma-amino-butyric-acid (GABA) effects. 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), vasoactive 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.<sup>70,71,72,73</sup>

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.<sup>74</sup> This idea is further supported by evidence that acupuncture increases  $\mu$  opioid receptor binding potential, allowing for effective analgesia at lower doses of OLM.<sup>75</sup> For patients not yet prescribed OLM, acupuncture should be recommended prior to OLM prescription commencing. This would be in-line with existing guidelines, such as those by the ACP<sup>76</sup> and the Centers for Disease Control and Prevention (CDC),<sup>77</sup> which recommend that safe and effective non-opioid alternatives should first be exhausted before resorting to OLM.

It is important to note as well that opioids as a monotherapy are often not as successful as may be thought in the general public perception. A recent systematic review of opioid analgesics for low back pain, which included 7,925 participants, found that opioids were poorly tolerated and for those who tolerate them the effect is unlikely to be clinically important within guideline recommended doses.<sup>78</sup> The first ever randomized controlled trial evaluating the long-term effectiveness of opioids, found that those on long-term opioid analgesia were actually in marginally more pain at 12 months than those in the non-opioid group.<sup>79</sup> Hence, complementary methods of pain control are critical to successful patient management.

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

Adverse neuroplastic changes can present a challenge in pain management, as maladaptive neuroplasticity can be associated with severe chronic pain that is resistant to treatment. Via peripheral stimulation, acupuncture may relieve the symptoms of patients affected by problematic neuroplastic changes. There is evidence that acupuncture has the capacity to reverse adverse neuroplastic changes in the dorsal horns of the spine, as well as in the somatosensory cortex.<sup>80,81,82,83</sup> 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.**

Acupuncture is an effective way to treat opioid addiction. There are more than 45 human and animal studies and clinical trials included in the PubMed database exploring acupuncture's role in minimizing the usage of multiple drugs of potential abuse including opiates and methamphetamine.<sup>84</sup> In 1973, Doctors Wen and Cheung, et al. from Hong Kong published an accidental finding that ear acupuncture treatment for respiratory patients had apparently alleviated opioid withdrawal signs and symptoms.<sup>85</sup> These findings were replicated by others around the world, including in New York and Sydney in the mid-1970s. In 1985, Dr. Michael Smith, et al. in New York established the National Acupuncture Detoxification Association (NADA), which today operates in over 40 countries with an estimated 25,000 providers. There are more than 1,000 programs in the U.S. and Canada that now use acupuncture to help addicts overcome their addictions.<sup>86</sup> Acupuncture for addiction is a versatile modality that can be effortlessly integrated into many environments including prisons, in- and outpatient programs, community centers, disaster relief, and humanitarian aid efforts. Furthermore, acupuncture addiction protocols can address acute and prolonged withdrawal symptoms, stress and anxiety related to drug withdrawal, and help prevent relapse. Using drugs to treat those already drug addicted is not a rational plan of action, and finding sound, non-pharmacologic treatment options is of paramount importance.

A meta-analysis done in 2012 concluded that “the majority [of studies] agreed on the efficacy of acupuncture as a strategy for the treatment of opiate addiction” and that “neurochemical and behavioral evidence have shown that acupuncture helps reduce the effects of positive and negative reinforcement involved in opiate addiction by modulating mesolimbic dopamine neurons. Moreover, several brain neurotransmitter systems involving opioids and GABA have been implicated in the modulation of dopamine release by acupuncture.”<sup>87</sup> In a recent RCT involving 28 newborns with Neonatal Abstinence Syndrome, laser acupuncture plus OLM significantly reduced the duration of oral morphine therapy when compared to OLM alone.<sup>88</sup> The mechanism for acupuncture in opiate withdrawal was found to be mediated by the endogenous opioid “dynorphin” binding to kappa-opioid receptors.<sup>89</sup>

**5. Acupuncture has been recommended as a first line non-pharmacologic therapy by the FDA, as well as the National Academies of Sciences, Engineering, and Medicine in coping with the opioid crisis. The Joint Commission has also mandated that hospitals provide non-pharmacologic pain treatment modalities.**

The Food and Drug Administration (FDA) released proposed changes to its opioid prescription guidelines in early May 2017. This was titled as its “Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids”. The guidelines now recommend that doctors become informed about non-pharmacologic options for pain control to help avoid the overuse of opioids.<sup>90</sup> Per the FDA’s request, the National Academies of Sciences, Engineering, and Medicine (NASEM) released a report to outline the state of the science regarding prescription opioid abuse and misuse, as well as the evolving role that opioids play in pain management. The new NASEM report on pain management and opioids recommends more public education, reimbursement models, and support for non-drug approaches to pain treatment. It systematically summarizes the evidence for acupuncture’s clinical benefits in treating different pain conditions, and provides an overview of some of the basic science underlying acupuncture’s mechanisms in pain management.<sup>91</sup> Further, effective January 1, 2018, the Joint Commission has mandated that hospitals provide non-pharmacologic pain treatment modalities.<sup>92</sup> Acupuncture is ideally suited to fulfil this mandate. These official, evidence-based clinical guidelines are in line with global healthcare trends; as of November 2015, acupuncture had over 870 recommendations in official clinical guidelines for over 100 conditions from institutions in over 30 countries.<sup>93</sup>

**6. Among most non-pharmacological managements for pain relief now available, acupuncture therapy is the most effective and specific for opioid abuse and overuse.**

There are several forms of non-pharmacological managements for acute and chronic pain, including physical therapy, spinal cord manipulation, yoga, tai chi, and cognitive behavioral therapy. Among these therapies commonly recommended by medical authorities, acupuncture is the most specific in targeting the endogenous opioid system. There is more evidence that acupuncture can induce endorphins to cope with acute and chronic pain in basic research than for any other non-pharmacological approach for pain.<sup>94,95,96,97</sup>

**7. Acupuncture is widely available from qualified practitioners nationally.**

In 2013 more than 28,000 licensed acupuncturists were estimated to be practicing in the U.S., with many more in training.<sup>98</sup> A 2015 study found the number of trained practitioners to be approximately 34,400. The number of licensed acupuncturists was noted to have increased by 23.3% and 52.1% compared to the years 2009 (n=27,965) and 2004 (n=22,671) respectively.<sup>99</sup> Currently the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) has 57 schools in its membership,<sup>100</sup> with approximately 10 schools offering doctoral degrees. The National Certification Council for Acupuncture and Oriental Medicine (NCCAOM) has certified more than 18,000 practitioners for minimal competency.<sup>101</sup> The American Academy of Medical Acupuncture

also represents more than 1,300 medical doctors trained to offer acupuncture services, and has approved nine programs for medical doctor certification in acupuncture.<sup>102</sup> One certification program alone has trained more than 6000 physicians in medical acupuncture,<sup>103</sup> so a conservative estimate of the total number of physicians trained would be approximately 10,000, though the number in active practice with acupuncture is unknown. Most states allow physicians to practice acupuncture, with some specifying additional training.<sup>104</sup> Increased coverage and demand for acupuncture will lead to a greater supply of providers as well. As noted above, NADA providers are estimated at 25,000 individuals, with more than 1,000 programs in the U.S. and Canada.

**Appendix 1. Effectiveness of Acupuncture.**

<b>Author, Year</b>	<b>Topic/Intervention</b>	<b>Participants/Population</b>	<b>Primary Outcomes</b>	<b>Key Findings</b>	<b>Study Quality</b>
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
Gadau 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 controls in various combinations in labor pain	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 length of labor	Conflicting evidence
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, 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 electro-acupuncture 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)/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

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# Evidence-Based Nonpharmacologic Strategies for Comprehensive Pain Care

## The Consortium Pain Task Force White Paper

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**The Academic Consortium for Integrative Medicine & Health (the Consortium) is a 72 North American institutional member organization of esteemed academic medical centers and health systems whose mission is to advance evidence-based integrative medicine and health in research, curricula and sustainable models of clinical care.**

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## ABSTRACT

Medical pain management is in crisis: from the pervasiveness of pain to inadequate pain treatment, from the escalation of prescription opioids to an epidemic in addiction, diversion and overdose deaths. The rising costs of pain care and managing adverse effects of that care has prompted action from state and federal agencies including the DOD, VHA, NIH, FDA and CDC.

There is pressure for pain medicine to shift away from reliance on opioids, ineffective procedures and surgeries toward comprehensive pain management that includes evidence-based nonpharmacologic options. This White Paper details the historical context and magnitude of the current pain problem including individual, social and economic impacts as well as the challenges of pain management for patients and a healthcare workforce engaging prevalent strategies not entirely based in current evidence. Detailed here is the evidence-base for nonpharmacologic therapies effective in post-surgical pain with opioid sparing, acute nonsurgical pain, cancer pain and chronic pain. Therapies reviewed include acupuncture therapy, massage therapy, osteopathic and chiropractic manipulation, meditative movement therapies Tai chi and yoga, mind body behavioral interventions, dietary components, and self-care/self-efficacy strategies.

Transforming the system of pain care to a responsive comprehensive model necessitates that options for treatment and collaborative care must be evidence-based and include effective nonpharmacologic strategies that have the advantage of reduced risks of adverse events and addiction liability.

The evidence demands a call to action to increase awareness of effective nonpharmacologic treatments for pain, to train healthcare practitioners and administrators in the evidence base of effective nonpharmacologic practice, to advocate for policy initiatives that remedy system and reimbursement barriers to evidence-informed comprehensive pain care, and to promote ongoing research and dissemination of the role of effective nonpharmacologic treatments in pain, focused on the short and long term therapeutic and economic impact of comprehensive care practices.

## SECTION 1: THE PROBLEM

### HISTORICAL CONTEXT FOR A CALL TO CHANGE

Pain care in America is in crisis. The prevalence of pain is high despite costly, well-intentioned medical responses, which rely mainly on pharmaceuticals and high-tech interventions. Pain and aspects of current pain management strategies are having enormous deleterious impacts on patients, the health system and society.<sup>1,2</sup> From the 1970s to the 1990s there was hope that new drugs, more liberal use of opioids, new technologies and a growing understanding about the mechanisms of pain would reduce the occurrence of uncontrolled pain. This was not the case. Growing rates and escalating costs of pain-related morbidity, mortality and disability have led to calls for culture change in pain medicine by The Office of the Army Surgeon General Pain Management Task Force (PMTF) Report,<sup>3</sup> Institute of Medicine (IOM) (now the National Academy of Medicine, NAM),<sup>1,2</sup> Interagency Pain Research Coordinating Committee's National Pain Strategy,<sup>4</sup> and others. Government leaders have declared the opioid crisis a national emergency. The recommendations consistently promote a shift toward a more comprehensive, patient-centered and health-focused approach to pain patients. In this model, collaborative care is team-based, interdisciplinary, and involves both pharmacologic and nonpharmacologic approaches. The model affirms the essential role patients have in improving their own health and pain-related behaviors. There is a growing recognition that current conventional medical treatment may not be the best starting point and is often not sufficient. In addition to inadequately addressing pain there is increasing evidence that conventional treatment strategies are fueling the opioid crisis, according to a National Institute for Drug Abuse (NIDA) report citing one in three Americans used prescription opioids for pain in 2015.<sup>5</sup> Moreover, evidence-based nonpharmacologic approaches may be the more appropriate initial treatment for acute and chronic pain management.

Currently there is no clear roadmap for a comprehensive approach to pain management that includes evidence-based nonpharmacologic strategies. The goal of this white paper is to outline the role of evidence-based nonpharmacologic strategies for the management of pain and how they can best be integrated with conventional approaches. This integrative pain management approach is in alignment with the stated goals of the reports from the Office of the Army Surgeon General PMTF, NAM, National Academies of Science and the NIH National Pain Strategy. How pain is assessed, managed and taught to health professionals must be updated. A shift is essential to address the immense deleterious impact that pain and the current system of pain care, including opioid reliance, have on patients, the health system and society.

## Magnitude of the Pain Problem

### Societal impact

The morbidity, disability and economic costs of pain in America are enormous. Recent estimates for the cost of pain care fall in the vicinity of \$560-635 billion annually.<sup>1</sup> This exceeds the annual expenditures for heart disease, cancer and diabetes combined, the nation's priority health conditions.<sup>6</sup> The IOM report estimated over 100 million American adults suffer from chronic pain. This figure is likely an underestimate of America's overall pain burden, as it does not include children, nursing home residents, active military, or those in prison.<sup>1,2</sup> The prevalence of chronic pain conditions in the general adult U.S. population is estimated to range from 11-47% in large surveys.<sup>1,6-11</sup> Low back and neck pain, osteoarthritis (OA), and headache are the most common pain conditions in the U.S and are leading global causes of disability in 2015 in most countries.<sup>12</sup> Unfortunately, we can expect the chronic pain burden to escalate. A 2013 National Academy of Sciences report predicts pain prevalence will rise as chronic illnesses increase.<sup>13</sup> For example, neuropathic pain currently affects over six million Americans and is expected to rise dramatically due to the increasing prevalence of diabetes. Obesity is also increasing and is associated with risk of diabetes, neuropathy and orthopedic problems.<sup>1</sup> Inadequate post-surgical pain management strategies for the increasing numbers of ambulatory and outpatient surgeries have resulted in chronic pain. As surgical, anesthetic and pharmaceutical interventions save lives in cases of catastrophic injury and life threatening illness there is another growing cohort of people who are living with chronic pain.<sup>1</sup>

While pediatric pain statistics are less well studied, a systematic review of the epidemiology of chronic pain in children and adolescents found that 'persistent and recurrent chronic pain is overwhelmingly prevalent in children and adolescents and should be recognized as a major health concern in this population'.<sup>14</sup> The most common pediatric chronic pain complaints include migraine, recurrent abdominal pain and general musculoskeletal pain, including limb pain and back pain.<sup>15</sup> Depending upon the population surveyed and time frame of the survey, prevalence estimates for pediatric chronic pain range from 4-89%: headache (8-83%), abdominal pain (4-53%), back pain (12-24%) , musculoskeletal pain (4-40%), and 'other' or general pains that included recurring earaches, throat pain.<sup>14</sup>

### Impact of pain: individual, workplace and employer health costs

The impact of pain is felt at many levels ranging from the effects on the individual, families, the healthcare system, employers and the community at large. Chronic pain is a high impact disruptor of lives and economies. It is complex—physically, neurologically, psychologically, socially, spiritually, economically, and symbolically.<sup>16</sup> For the individual, there may be decreased physical functioning and increasing difficulties with simple daily and self-care activities.<sup>17</sup> These changes can have an impact on psychological health, with an increase in sadness, worry, anger, depression, suicidal thoughts, and a reduced sense of self-worth with

changes in abilities.<sup>18</sup> For children, there may be an impact on school performance, school attendance, and interactions with peers.<sup>14,19</sup> For both adults and children, pain negatively impacts social functioning and relationships. As a result of alterations in work capacity, people in pain have lower hourly wages and miss more time from work than those without pain.<sup>6</sup> In some cases pain leads to the need for work modifications or disability claims. Pain is associated with impairment in physical and psychological functioning,<sup>12,20</sup> lost work productivity,<sup>21</sup> and lower socioeconomic status.<sup>22</sup> In addition to the costs and time needed for seeking care, people with pain conditions have significantly higher direct healthcare expenditures.<sup>6</sup>

### **Opioid abuse/dependence impact on health care costs**

Among the distinctions of the current epidemic from earlier opioid abuse epidemics is that this crisis, having been based in medical prescribing, is disproportionately affecting white, middle-class people in non-urban settings, including those with private insurance.<sup>23</sup>

- 2007-2014, opioid dependence rose by 3,203% among patients privately insured<sup>23</sup>
- 2011-2015 privately insured opioid abuse or dependence charges rose from \$72 million to \$722 million.<sup>24</sup>
- Allowed amounts for opioid abuse/dependence health care services grew more than thirteen-fold during the same period, from \$32 million in 2011 to \$446 million in 2015.
- In 2015, the average annual per-patient charges and estimated allowed amounts by insurance were more than five times higher for patients with diagnoses of opioid abuse or dependence than for those with any diagnosis.
- In 2015, private insurers and employers providing self-funded plans paid nearly \$16,000 more per patient with a diagnosis of opioid abuse or dependence than for those with any diagnosis.<sup>24</sup>
- 2006-2010 emergency department (ED) visits related to prescription opioid poisoning increased to 259,093; over half were hospitalized resulting in over \$4 billion in costs.<sup>25</sup>
- ED visits for pediatric opioid poisoning between 2006 and 2012 numbered 21,928 with over \$81 million in total charges.<sup>26</sup>
- From 2007-2014 pregnancy drug dependence diagnosis (including prescription opioid) rose 511%.<sup>23</sup>
- From 2003-2012, neonate abstinence syndrome (NAS) admissions increased more than four-fold with annual costs growing from \$61 million to nearly \$316 million.<sup>27</sup>
- Hospital stay is 3.5 times longer for NAS neonates compared to non-NAS neonates, with a three-fold increase in cost.<sup>27</sup>
- A sizable percentage of the driving public has detectable levels of opioids in their blood<sup>28</sup> with opioid impaired driving implicated in motor vehicle accidents.<sup>29</sup>

These costs and risks are substantial and yet fail to measure the costs to the health and wellbeing of society: communities, families, friendships and individuals.

## Economic impact of pain

The US spent 17.8% of the GDP on healthcare in 2015,<sup>30</sup> expected to increase to 20% or higher by 2025.<sup>31</sup> A significant portion of that is pain related since pain is the most common and compelling reason for seeking medical attention.<sup>32,33</sup> ‘The economic burden of prescription opioid overdose, abuse and dependency is estimated to be \$78.5 billion each year in the US.’<sup>34</sup> Social Security Disability Insurance statistics suggest that worker disability from musculoskeletal and connective tissue disorders is rising, not falling. Work disability attributed to musculoskeletal and connective tissue disorders increased from 20.6% of beneficiaries in 1996 to 25.4% in 2005<sup>35</sup> to 31.7% in 2015.<sup>36</sup> In addition to worker disability there are direct and indirect workforce financial costs including both workplace absenteeism<sup>2</sup> and lost productivity from ill and injured workers while still working, called presenteeism.<sup>37,38</sup> There can be lost business opportunities and reduced customer goodwill due to work that goes undone and deadlines, meetings, appointments or engagements missed due to employee absence or reduced capacity. The Integrated Benefits Institute (IBI) (2005) conducted a landmark and ubiquitously cited survey in 2006: nearly all CFOs surveyed (343 senior finance executives) reported that they will focus on controlling health plan costs over the next two years because they believe that work time lost to employee illness including chronic pain is reaching critical levels and is affecting business performance.<sup>39</sup> A majority will seek to manage all health-related costs, including absenteeism and bottom-line effects as key impacts of employee ill health. IBI also found, however, that CFOs are ill-informed about health-related lost work time. Nearly half of survey respondents never receive reports about ‘incidence of absence’, and less than a quarter receive reports on its financial impact. Far fewer know about presenteeism with nine in ten never receiving reports on the incidence or impact of presenteeism in the organization.

Cost savings from improving worker health requires new record keeping strategies. One of the most significant new research models is the extension of return on investment (ROI) analyses to include economic outcomes resulting from health interventions such as performance and productivity. For example, while very few newly approved pharmaceuticals actually save money, they can improve health at a reasonable cost. In pharmacy literature, net increases in spending that are up to \$50,000 may be deemed acceptable or cost-effective if these dollars will save at least one quality-adjusted year of life (QALY). However, this widely accepted methodology has rarely been used when considering the value of health improvement programs.<sup>40</sup> By contrast, the more demanding objective of realizing net savings has generally been required in evaluations of health and productivity management programs.<sup>41</sup> Companies with successful wellness programs, with improved health-related and economic outcomes, encouraged wellness to improve employees’ lives not only to reduce costs.<sup>42</sup> Furthermore, employers and payers need to realize that benefits of investments in health accrue over time, and there may be a lag between improvements in health and savings from improved productivity. Standard calculations of documenting ROI may need to become more sophisticated to capture net cost savings in the intermediate and long run.

The current workforce literature is inadequate to evaluate the specific role of pain as distinct from overall illness. The literature on work-related injuries such as back, neck and upper

limb pain covers a subset of pain problems but does not capture data on such pain-related conditions as arthritis, autoimmune disorders, and diabetic and other neuropathies that are not work related. The current lack of clarity of clinical and especially cost implications remains to be resolved by future, more rigorous studies conducted at worksites over multiple years with adequate follow up times to determine both clinical and cost benefits.<sup>43,44</sup> Ongoing studies seek to develop best practice models for business analysis outcomes. Recent reviews confirm that companies that invest in worker health and wellbeing, including through health-promotion programs, have markedly improved stock price performance compared to the Standard and Poor's 500 Index (S&P).<sup>45,46</sup> Similar savings have also been observed through health promotion programs among individuals who are retired and on Medicare.<sup>47</sup>

## **Health disparities and pain: race/ethnicity, gender and age**

Pain and pain care impact specific socioeconomic and demographic groups differently. Increased vulnerability to pain is associated with having English as a second language, race and ethnicity, lower income and education, sex and gender, age group, geographic location, military veterans, cognitive impairments, surgical patients, cancer patients, and the end of life.<sup>1</sup> Many of these same groups are also vulnerable to pain treatment that is limited in access and scope.<sup>1,2,48</sup> In addition to factors such as age, race/ethnicity, socioeconomic status, gender and geography, education and health literacy also influence access to kinds of care and to care outcomes. For example, while back pain is common across all primary care populations, low-income, racially diverse individuals are impacted differently. African Americans have a lower likelihood than whites of receiving comprehensive pain assessment and management.<sup>48</sup> African Americans may also receive less intensive diagnostic and treatment approaches compared to white patients.<sup>48</sup> For occupation-related back pain, whites are more likely to be diagnosed with disc herniations and have surgery than blacks; yet a nonspecific diagnosis and lack of surgery uniquely predicts lower treatment expenditure and disability ratings for African Americans.<sup>49</sup> Perversely, it is possible that this disparity in care provides an advantage to those African Americans who might ostensibly be considered 'undertreated': less treatment for back pain may be better treatment.<sup>35</sup>

This does not, however, erase the sting of discriminatory care. Episodes of major lifetime racial discriminatory events are the strongest predictors of back pain reported in African-Americans, with perceived day-to-day discrimination being the strongest predictor of back pain for African American women.<sup>50</sup> Racial discrimination as a predictor of pain is consistent with the impact of social context and its interrelationship with chronic pain.<sup>51</sup> Older African Americans experience severe mismanagement of pain and potentially inappropriate or dangerous medication duplication or interactions, particularly those with comorbidity, multiple providers and limited access.<sup>52</sup> Patients of lower socioeconomic status and lower health care literacy are less likely to be able pursue effective healthcare options not typically covered by insurance. There is ongoing research to assess how disparities in health care and outcomes operate along ethnic and socioeconomic lines. A recent review of long-term survey data indicates that racial/ethnic

disparities in pain may be in part accounted for by socioeconomic status and education level—both factors that interact with race and ethnicity.<sup>11</sup>

Hispanics are at higher risk for pain and pain undertreatment given the incidence of lower education, income levels, and lack of health insurance and/or access to care. These disadvantages are further compounded when there is limited English proficiency that impacts communication with health care providers.<sup>1</sup> American Indians and Alaska natives have markedly higher rates of pain symptoms compared to U.S. general population,<sup>53</sup> with high rates of diseases and health conditions such as diabetes, arthritis and obesity that produce significant pain.<sup>1</sup> Despite this, American Indians report minimizing pain complaints and not readily asking for help, likely exacerbating disparities through underdiagnosis and undertreatment.<sup>54</sup> Asian Americans have overall lower pain prevalence than non-Hispanic whites. However, the variety of national origins, cultures, languages and ethnicities lead to variations within this group. Lower reports may be due to a general reluctance to report pain (perceived as a sign of weakness) and a fear of side effects of pain medication combined with the potential liability of lower English proficiency and the experience of cultural bias by health professionals.<sup>1</sup>

In every ethnic/racial category, women are more likely than men to report a wide range of chronic pain conditions<sup>1,55,56</sup> while pain prevalence varies for women by age and race/ethnicity.<sup>57</sup> Women experience disparities in pain care with misdiagnoses, delays in correct diagnoses, improper and uneven treatment, gender bias, stigma and neglect, and dismissal and discrimination from the health care system.<sup>1,58</sup> Women report greater severity, longer-lasting and more frequent pain than men, and also experience multiple pain problems. Women are prescribed opioids and benzodiazepine sedatives at higher rates than men.<sup>59,60</sup> While men are more likely than women to die from prescription opioid painkillers, the percentage increase in deaths since 1999 is over fivefold greater among women.<sup>61</sup> Between 1999 and 2010, about 18 women died every day in the U.S from a prescription opioid overdose. For every woman who died of an overdose, there were 30 who went to the emergency department for painkiller misuse or abuse.<sup>61</sup>

Chronic pain in children is often underrecognized<sup>1</sup> and even when recognized is still undertreated, with consequences that include behavioral changes and adverse effects on child development.<sup>62</sup> While both boys and girls are more at risk of chronic pain as they get older, girls report chronic pain more often than boys.<sup>14,63</sup> Undertreated pain is also common among hospitalized children.<sup>64</sup> There are many levels at which children may receive disadvantaged care.<sup>65</sup> Many pain medicines have not undergone clinical trials or been approved for pediatric use and consequently providers are more reluctant to administer them.

The prevalence of chronic pain among independent living older adults ranges from 18 % to 57%, depending on the definition of chronic pain. More severe pain and pain that interferes with activities increases with age.<sup>1</sup> Additionally, there may be difficulty assessing pain in older adults with cognitive impairment. Side effects of drug treatment may further adversely affect their cognitive function and overall health.<sup>66-68</sup>

Easy access to opioids as the main pillar of pain care can be viewed as inadequate or ‘disadvantaged’ care based on the lack of evidence for safety or effectiveness for chronic non-cancer (CNCP) pain.<sup>69,70</sup> This is further reinforced by opioids’ abuse liability. The successful marketing of opioid dose-escalation for CNCP has adversely affected those traditionally considered disadvantaged as well as those who are not.

The perfect storm of circumstances, with opioids for CNCP promoted by physicians<sup>71</sup> and pharma alike, opened the floodgates to single modality care with opioids creating an addiction crisis<sup>72</sup> with a staggering impact on, for example, unemployed and disabled workers in economically devastated industrial communities.<sup>73</sup> White, middle-class people in non-urban settings are disproportionately affected by the current opioid crisis. Between 2007-2014, opioid dependence rose by 3,203% among patients privately insured in these communities.<sup>23</sup> Effective pain care is not assured by economic access to care, for example, through private insurers.<sup>13</sup>

While the 2016 Centers for Disease and Control (CDC) guidelines confirm non-opioid therapy is preferred for chronic pain outside of active cancer, palliative and end-of-life care,<sup>74</sup> for these populations pain is often the dominant symptom<sup>1</sup> and there is substantial evidence that nonpharmacologic therapies can play a significant role in cancer pain, palliative and end of life pain care as well.<sup>75-77</sup>

Taking into account all health care disparities and the current U.S. crisis in pain care, a case can be made that any patient no matter their ethnic or socioeconomic status, who is not informed or who is not offered effective nonpharmacologic options for pain is, in fact, inadequately served. One could argue that given the risks of standard care, failing to educate patients and recommend nonpharmacologic care should be considered unethical.

## Complexity of pain categorization

There is tremendous variability in the categorization of pain states that can obscure the magnitude of the problem of pain management. Pain is commonly categorized into acute and chronic, according to timeline and connection to tissue injury. Acute pain typically lasts less than 3 months but may persist longer and usually has a clear connection to a physically identifiable nociceptive (pain generating) pathology or tissue damage.<sup>78</sup> Acute pain is expected to resolve as the tissue damage heals. Chronic pain is present for longer than 3 months and may or may not have a clear and current connection to an identifiable tissue-based cause, structural injury or defect. Cancer pain can be acute, whether it is post-surgical or due to ongoing nociception, or can be chronic. The timeline of a pain condition is increasingly being recognized as an artificial metric, as the distinguishing features of the mechanisms of acute and chronic pain are recognized. For chronic pain, the search for causative physical sources can be frustrated by many factors, including the lack of sensitivity of available imaging technology to detect soft issue and neuropathic causes, the complex structures that can be involved in the generation and modification of pain, and the limited training most doctors receive in the subtleties of physical examination for pain conditions.<sup>79,80</sup> Physicians report wanting more training and knowledge on evidence-based nonpharmacologic therapies and are not aware of evidence-based resources.<sup>81</sup>

‘Any meaningful effort to improve pain management will require a basic culture shift in the nation’s approach to mandating pain-related education for all health professionals who provide care to people with pain’.<sup>82</sup>

More recent discoveries about central and peripheral nervous system pain processing (central sensitization and peripheral sensitization) are being recognized as more actionable when classifying pain. Central sensitization involves neuronal and non-neuronal pathways (example, glial pathways) to and from the brain and spinal cord.<sup>83</sup> Peripheral sensitization involves peripheral structures such as muscle, nerve, fascia and others.<sup>84,85</sup> In both central and peripheral sensitization, decreased inhibitory signals meant to downregulate nociceptive transmission are themselves inhibited, leading to enhanced perception of pain. This presents clinically as hyperalgesia (experiencing a mildly painful stimulus as very painful) and allodynia (experiencing non-painful stimuli as painful). The phenomena of peripheral sensitization are increasingly recognized in the medical community and well documented in basic science literature.<sup>84,85</sup> Another increasingly recognized neuroplastic process is the reorganization of the somatosensory cortex leading to altered and inefficient movement strategies, which can themselves cause fatigue and pain.<sup>86,87</sup> These changes in the nervous system currently inform our perceptions of chronic pain and are seen in many common chronic pain syndromes, including headache; back and neck pain; chronic abdominal pain; fibromyalgia and chronic fatigue; visceral pain; and the group of conditions called repetitive strain injuries such as cervical postural syndrome, most cases of thoracic outlet syndrome, carpal tunnel disorders, trigger fingers, and forearm and thumb tendonitis.

Pain can also be subcategorized according to anatomical sites where the pain is felt such as headache, neck and back pain. Pain can be named for the tissues involved such as musculoskeletal, visceral, or neuropathic. It can be named for the pathological process such as cancer pain, osteoporotic pain, OA pain, repetitive strain injury or post-surgical pain. Many of these categories of pain can coexist and even overlap, making it important to understand the parameters and definitions used with studies evaluating pain statistics. Regardless of classification systems, the number of people in pain is high and increasing.<sup>1,7-10</sup> Moreover, chronic pain states have the highest economic and societal adverse impacts.

## **Co-morbidities associated with pain**

The definition of pain commonly used in hospice was proposed by Dame Cicely Saunders, and includes the physical, psychological, social, and spiritual domains.<sup>88</sup> This inclusive definition can be helpful in thinking about non-terminal cases involving pain since co-morbidities spanning Saunders’ domains are common in chronic pain patients and can complicate the evaluation and successful treatment of pain. There is a complex association between pain and psychiatric disorders. Adults with mental health disorders are significantly more likely to be prescribed opioids; 16% of Americans who have mental health disorders receive over half of all opioid prescriptions.<sup>89</sup> Patients with chronic pain are at increased risk of comorbid depression, anxiety and post-traumatic stress disorder.<sup>32,90</sup> Pain increases depression

risk 3-5 fold.<sup>91</sup> Pain, rather than chronic disease, is associated with the recurrence of depressive and anxiety disorders;<sup>20</sup> 50-80% of chronic pain patients report insomnia of a severity that warrants clinical attention.<sup>92</sup> However, opioids generally exacerbate rather than improve these sleep and mental health comorbidities.<sup>93</sup>

There are many interconnections between social rejection or exclusion and pain; for example, both are experienced in the same parts of the brain.<sup>51</sup> Social isolation is a common condition among pain patients. Pain itself isolates the individuals since they may withdraw from family, work, school and social activities. Pain medications, however, can exacerbate rather than improve isolation by interfering with hormonal and neurotransmitter functions.<sup>94</sup> The endogenous opioid system is involved in the development and maintenance of human attachment. According to the brain opioid theory of social bonding,<sup>95,96</sup> beta endorphins attach to mu opioid receptors resulting in analgesia and feelings of wellbeing. These are closely related to the dopamine reward system and the oxytocin system affecting bonding, reinforcing the rewarding nature of close social interactions.<sup>97-99</sup> The disruption of these interconnected functions—human social bonding, parent-infant bonding, the endogenous reward system which includes sexual response—by exogenous opioids is currently being studied extensively. Hypogonadism as a result of long term opioids has long been recognized.<sup>100</sup> The measure of the social dysfunction seen with opioid use is far reaching and has not been adequately addressed within in most clinical practice settings.<sup>99</sup>

As discussed above, substance use disorders (SUD) commonly occur and have increased as a result of the liberal use of prescription opioids. These may result from preexisting SUD or be iatrogenically induced dependence, tolerance and addiction to prescribed opioids. For a brief time, the term ‘pseudo addiction’ was used to justify the prescribing of higher opioid doses while ignoring ‘red-flag’ signs of addiction such as lost prescriptions, requests for early refills, and non-adherence with prescribed doses.<sup>101</sup>

In studying the association of prolonged opioid use with psychiatric co-morbidities, there is an ‘adverse selection’ at play; people with serious psychiatric co-morbidities are more likely to end up on high dose, long term opioids.<sup>102-105</sup> This could be in part a result of the difficulty accessing behavioral health and addiction services as well as the need to present with physical symptoms to obtain care. Opioids are being used as a proxy treatment, a convenient but risky option for complex pathologies that are characterized and labeled as ‘pain’ by patients and practitioners.<sup>102</sup> The social services needed to fully assess and treat them are often unavailable.

Pain interacts with overall health. Other comorbidities such as diabetes, cardiovascular disease and obesity are at once the cause of certain types of pain and exacerbated by pain.<sup>1</sup> Illnesses that are comorbid with pain can, in turn, be exacerbated by the use of opioids that are ineffective for chronic pain, produce illness behavior and carry a significant abuse liability.

## Healthcare workforce considerations

Many factors contribute to the current trends in pain management. The majority of medical/healthcare visits are initiated because of pain<sup>32-35</sup> and as a result, primary care practitioners (PCPs), family medicine, general internal medicine, general pediatrics, combined medicine-pediatrics, general obstetrics and gynecology, osteopathy, and general surgery assisted by nurses, nurse practitioners (APRN) and physicians' assistants (PAs) care for the largest proportion of those with pain and prescribe the largest proportion of pain medications including opioids.<sup>106-108</sup> The current business model for most primary care settings encourages short appointments to increase the volume of patients seen. Pain patients, especially chronic pain patients, have complex medical histories and often have multiple overlapping causes of pain. These presentations place an intense time pressure on PCPs making it difficult for them to fully address the complexities of chronic pain and may encourage therapeutic choices that can be easily recommended within the time allotted, most commonly prescription drugs. In 2012 nearly 49% of all dispensed opioid prescriptions were accounted for by primary care specialists.<sup>2</sup>

Additionally, the education currently provided to PCPs is deficient in content related to pain in general and the full spectrum of evidence-based pain care approaches. Pain curricula in medical school education for both MDs and DOs in the U.S. ranges from 1-31 hours during the 3-4 year curriculum, with a mean of 11.13 hours and a mode, or common length, of four 4 hours.<sup>109</sup> Residency education is also insufficient to prepare primary care practitioners for competency in the treatment of common pain problems.<sup>1,110</sup> 'A lack of knowledge and/or evidence of clinical effectiveness preclude the delivery of adequate care.'<sup>110</sup> 'Thus, the current training system has left primary care practitioners with inadequate tools with which to deal with some of their most frequent and challenging patients.'<sup>80</sup> 'Any meaningful effort to improve pain management will require a basic culture shift in the nation's approach to mandating pain-related education for all health professionals who provide care to people with pain.'<sup>82</sup>

Other medical specialists also treat pain that is within the purview of their specialty on a regular basis. Examples of this are urologists treating kidney stones and their painful sequelae or orthopedic surgeons treating post-operative pain. Generally, these specialists will treat pain for a short term and then return the patient to primary care or specialty pain care. Other specialties such as rheumatology, sports medicine, and physical medicine and rehabilitation (PM&R) sometimes have long-term engagement with pain care for their patients, mainly with interventional and pharmacologic options.

The medical pain specialty grew out of the work of John J. Bonica who directed the Department of Anesthesiology and Pain Medicine at the University of Washington in the 1960s. Many, if not most, pain clinics are still housed in anesthesiology clinics, but fellowship pain training can now be pursued not only by anesthesiologists but other specialists in neurology/psychiatry, PM&R, and internal and family medicine. Physicians who receive fellowship training in pain care learn interventional pain strategies that originated in regional anesthesia and acute pain care. Acute pain interventions are an essential part of pain care. But the expansion of these strategies, which are the mainstay of anesthesiology and acute pain practices, to chronic pain care have had more modest success and only in carefully selected patient

groups.<sup>111</sup> Additionally, there are licensed practitioners from evidence-based disciplines, as in acupuncture therapy, massage therapy, osteopathic therapy, chiropractic and others, providing pain care but whose work may currently be less accessible within most formalized health systems.

Another way to categorize the practitioners in the pain field is through insurance reimbursement. Some practitioners are typically insurance reimbursable such as physical therapists, psychologists, psychiatrists, social workers and dentists, and under certain circumstances, pharmacists. Practitioners licensed in fields such as acupuncture, massage, chiropractic, and naturopathy provide care that 60-70% less likely to be reimbursed.<sup>112</sup> Even when health coverage is available it is generally limited, such that patients will still have substantial out-of-pocket costs.<sup>113</sup> There are also studied approaches to pain care that are not regulated but are delivered by licensed practitioners ‘in place’ such as nurses using guided imagery or progressive relaxation, for example. These services are generally not reimbursed.

The need for an informed strategy including all evidence-based comprehensive pain care is clearly demonstrated to be in patients’ best interest, as reflected by their health care seeking and out-of-pocket expenditures for pain care. Reported in 1993 the number of visits to what were called ‘unconventional’ providers exceeded visits to all US primary care physicians; 1990 expenditures were 13.7 billion, 10.3 billion of which was out of pocket.<sup>114</sup> Analysis of the 2012 National Health Interview Survey estimated the out-of-pocket expenditure at \$30.2 billion.<sup>115</sup> Out-of-pocket expenditures for back pain alone was \$8.7 billion.<sup>113</sup>

Coordination of care across disciplines and access to nonpharmacologic care have not been optimized in the current system in most states and territories. There are a few state Medicaid policy initiatives aimed at increasing access to effective nonpharmacologic therapies as a first line treatment for pain conditions. For example, the Oregon Health Plan (OHP – Oregon’s Medicaid program) covers acupuncture therapy, chiropractic and osteopathic manipulation, physical therapy and cognitive behavioral therapy for all back conditions. In addition, yoga, intensive rehabilitation, massage, and/or supervised exercise therapy are recommended to be included in the comprehensive treatment plans and will be provided where available as determined by each Oregon’s Coordinated Care Organization.<sup>116</sup> Vermont’s legislature is piloting a program where they will cover acupuncture therapy for back pain in a Medicaid population and monitor health outcomes and cost-effectiveness.<sup>117</sup> Private coverage of every category of licensed provider is mandated in the State of Washington, where the number of people using insurance benefits for care by these providers was similar to data by the National Health Interview Survey (NHIS); hence coverage did not lead to runaway utilization.<sup>118</sup> Musculoskeletal pain was the most common diagnosis for a visit. For insured patients with back pain, fibromyalgia and menopause symptoms, users of nonpharmacologic therapy providers had lower insurance expenditures than those who did not use them.<sup>119</sup>

Coverage for care is not current to the evidence-base detailed in Section 2 below. Diversity of practice and engaging multiple evidence-based disciplines is enthusiastically embraced in pain medicine as a concept. Yet without a strategy on evidence-based pain care both in terms of effectiveness and cost-effectiveness, patients are not well guided in options and are

often left to be the sole case managers for their own care as they navigate a system fragmented into silos.

Practitioners and patients are challenged by other barriers in access to nonpharmacologic options that are effective for pain. In addition to the socioeconomic, gender, and racial/ethnic disparities already detailed, geographic disparities exist in the numbers and locations of practitioners using nonpharmacologic options leaving many regions and populations underserved.<sup>120,121</sup> As of the writing of this paper there are ongoing meetings regarding Medicare and Medicaid coverage for licensed practitioners working within their state-regulated scope of practice and utilizing therapies proven effective for pain. The Joint Commission (TJC), which has long recognized nonpharmacologic approaches to pain, has now mandated that their accredited hospitals and facilities provide evidence-based nonpharmacologic options for pain, emphasizing the importance of options in comprehensive care. Strategies will be needed to facilitate both access and coverage to nonpharmacologic therapies.

## **Risk and lack of effectiveness of prevalent pain care strategies**

Despite increased medical expenditures for pain and technological advances such as magnetic resonance imaging, new medications and surgical approaches, the prevalence and impact of chronic pain is worsening rather than improving. Many factors have contributed to the current situation. Both patients and medical practitioners labor under the mistaken idea that most pain problems can be fixed by the doctor or surgeon with a drug or procedure. Medical school and graduate courses still emphasize a search for appropriate dosing of opioid medications rather than considering other options. The business model of medicine, the cultural authority of projected and perceived certainty, and the disempowered position of patients in pain has promoted simplistic solutions—albeit well-intentioned—to complex problems. Patients are often regarded as passive participants with little emphasis placed on self-care, on pain prevention, or therapies that engage preventive and self-care strategies, despite demonstrated longevity of benefit.

The increasing need to respond to poorly addressed pain resulted in the numeric quantification of pain. As the notion of pain as the ‘fifth vital sign’ took hold in the late 1990s, pain assessment became increasingly focused on a single dimension of patient status—the pain score on an 11-point, 0-10 rating scale; either a numeric rating scale with numbers marked on a 10cm line or the visual analogue scale like the Wong-Baker scale, usually a 10cm line with faces expressing levels of pain and no numeric markings on it.<sup>122</sup> By taking eyes off the more complex goals of quality of life and overall functional ability, the system inadvertently contributed to reduced functioning and increased suffering of pain patients.<sup>69</sup> The pressure to manage pain scores rather than to treat patients themselves has contributed to overprescribing opioids, widespread drug diversion which is engaging illegal sources for prescription drugs, the resurgence of heroin addiction, increasing disability from pain, and deaths from overdose.<sup>1,2,35,123,124</sup> Pain practitioners have long noted that pain scores do not deliver accurate information about the status of a patient. Scores vary inexplicably and alone do not inform

tailored, comprehensive and effective solutions. Pain scores do not capture level of function or quality of life (QOL) intrinsic to an experience of wellbeing that can be present despite high pain scores. The reduction of a patient's pain experience to pain scores led to a narrowly defined goal of pain score reduction in response to interventions.<sup>123</sup>

## Opioids and other drugs

The US prescribes 50 times more opioids than the rest of the world combined.<sup>72</sup> Between 1999 and 2010, opioid prescriptions in the US were enough to medicate every American adult with a standard pain treatment dose of 5mg of hydrocodone every 4 hours for a month.<sup>125</sup> This indicates a public health crisis as prescription opioids contribute to substance use disorder (SUD) or addiction. Prescription opioids are now the most frequent gateway drug to heroin. Inadvertent overdose deaths associated with prescription opioids exceed overdose deaths from heroin and cocaine combined<sup>125</sup> and in many states now exceed deaths from motor vehicle accidents.<sup>126,127</sup> Societal and family disruption, violence and insufficient resources to treat SUD have resulted.

Complications attributable to the rapid rise of opioid use for chronic non-cancer pain (CNCP) have led to an evidence based re-evaluation of the practice of prescribing ever-increasing doses of opioids that have known risks and unproven benefits.<sup>69,128</sup> This has finally propagated recommendations for a shift away from opioids and toward comprehensive, multi-modal evidence-based care. While the government has increased access to naloxone for the treatment of acute opioid toxicity (respiratory arrest), it is important to note that this is not a preventative strategy for the deepening opioid crisis.

Acute pain care can impact the development of chronic pain and disability and the development of opioid dependence, tolerance, addiction and diversion. Patients often receive long-term opioid therapy after an acute problem such as dental procedure, surgery or injury. Alarming numbers of patients then transition to chronic use after starting opioids for the short-term treatment of post-operative pain (27%) or injury-related pain (27%).<sup>129</sup> Pain relievers are the medications reported most often prescribed at hospital emergency and outpatient department visits.<sup>33</sup> Per the CDC, the economic burden of prescription opioid overdose, abuse and dependence is estimated to be \$78.5 billion each year in the US.<sup>34,130</sup> Moreover, misuse and abuse of prescription opioids costs the country an estimated \$42 billion a year in lost productivity.<sup>131</sup> Workers' compensation data from Washington State indicates that injured workers who are on opioids for over three months are unlikely to return to work.<sup>124</sup>

The probability of long-term opioid use increases after as little as five days of prescribed opioids as the initial treatment of pain; the probability of patients remaining on opioids for the long-term is the highest when treatment is initiated with long acting opioids,<sup>132</sup> a strategy borrowed from cancer pain treatment<sup>71</sup> and not well studied in non-cancer pain. Tolerance (requiring higher doses to achieve the same analgesic effect), dependence (suffering withdrawal symptoms if a dose is missed) and opioid induced hyperalgesia<sup>133</sup> (a heightened sensitivity to pain) can develop quickly. There is no clear way to ascertain what baseline pain is present and

what pain is in response to withdrawal from the last dose of opioid or induced by the opioid itself.

*Acetaminophen (APAP)* has been found to be only modestly helpful for mild pain; it is ineffective for acute low back pain,<sup>134</sup> and it is uncertain if it has any effect in chronic low back pain (cLBP).<sup>135</sup> Although there are fewer adverse events with acetaminophen than other medications,<sup>134</sup> there are dose limitations due to hepatotoxicity.<sup>68</sup> *Nonsteroidal anti-inflammatory (NSAID)* medications may be helpful in decreasing pain from a variety of causes such as arthritis, headache and back pain. More recent trials, however, report “that NSAIDs had smaller benefits for cLBP than previously observed”.<sup>134</sup> The benefit of NSAIDs for spinal pain compared to placebo were not clinically important.<sup>136</sup> NSAIDs are now recognized to interfere with healing<sup>137,138</sup> and cause of significant morbidity and mortality. They are a well-recognized cause of rebound headaches. Rebound pain, chronic medication use and discontinuation syndromes in other conditions have not been as widely studied but exist.<sup>139</sup> Many patients have difficulty tolerating NSAID medicines due to gastrointestinal side effects such as nausea and abdominal pain.<sup>140</sup> The FDA has issued new warnings on NSAIDs,<sup>66</sup> adding stroke and cardiac risk to the list of already well-known risks, which include delayed healing, renal failure and acute and chronic GI bleeding.<sup>2,68</sup> There are 16,500 deaths annually from NSAID associated GI complications among RA and OA patients alone.<sup>67,140</sup>

*Corticosteroid* medications are considered potent anti-inflammatories often prescribed orally or by injection for refractory neurologic and autoimmune related pain as in discogenic pain, rheumatoid arthritis and intractable headache. Recent studies challenge the usefulness of steroids for many indications including chronic pain.<sup>134,141</sup> One in five American adults in a commercially insured plan were given prescriptions for short term use of oral corticosteroids during the three-year period from 2012 through 2014.<sup>142</sup> Even at relatively low doses, corticosteroids can be associated with insomnia, nervousness, behavioral changes, increased appetite, headache and joint pain.<sup>143,144</sup> There are increased risks of serious acute complications such as infection, venous thromboembolism, avascular necrosis and fracture. There are also risks of development and or exacerbation of chronic disease such as diabetes mellitus, hypertension, osteoporosis, and other features of iatrogenic Cushing’s syndrome.<sup>142</sup> Corticosteroids are one of the most common reasons for admission to hospital for drug related adverse events.<sup>142</sup> Yet corticosteroids do not appear to be effective for acute, radicular or nonradicular low back pain.<sup>134,141,145</sup> Epidural steroid injections are associated with less improvement in patients with lumbar spine stenosis,<sup>146</sup> increased risk of spinal fractures,<sup>147</sup> and increased risk of infection if followed within three months by spinal fusion surgery.<sup>148</sup>

*Skeletal muscle relaxants* are prescribed for short-term pain relief in acute pain but are associated with central nervous system adverse effects, especially sedation.<sup>134</sup> Research is equivocal on significant benefit of some muscle relaxants for pain or muscle spasm.<sup>149</sup> Baclofen (oral, IV or intrathecal) can be helpful for neurologically mediated spasticity as in multiple sclerosis, traumatic brain or spine injury but with risk of increase in mean fat body weight<sup>150</sup> and serious complications, even organ failure, with disruption in administration.<sup>151</sup> Carisoprodol (Soma) should be avoided as it metabolizes to meprobamate, which has been withdrawn from the

market in many jurisdictions due to toxicity and respiratory suppression when combined with opioids. Benzodiazepines may provide some relief for nonradicular low back pain and muscle spasm.<sup>134</sup> However, common adverse effects include anticholinergic symptoms such as dry mouth, blurred vision, constipation, drowsiness, sedation and confusion. Adverse effects and risk of dependence are important limiting factors especially since there is a high prevalence of concurrent benzodiazepine and opioid use in patients with chronic pain.<sup>152</sup> Moreover, half of deaths from drug overdoses among veterans occurred when concurrently prescribed benzodiazepines and opioids.<sup>153</sup>

*Anticonvulsant (antiepileptic)* medications gabapentin and pregabalin are often used in neuropathic and neurological pain conditions such as diabetic neuropathy, postherpetic neuralgia and migraine and more recently in acute perioperative pain.<sup>2</sup> Topiramate and valproate/divalproex are commonly used for headache attenuation or prevention.<sup>154,155</sup> Though carbamazepine is commonly used in the treatment of trigeminal neuralgia evidence for its effectiveness is not strong.<sup>155,156</sup> These medications provide mild to moderate benefit while being limited by neurological adverse effects including drowsiness and cognitive slowing.<sup>157</sup>

*Antidepressants* of various classes including tricyclic, serotonin and norepinephrine modulators are commonly used in pain conditions including neuropathic, migraine and amplified pain disorders such as fibromyalgia and complex regional pain syndrome.<sup>158</sup> There is also a growing recognition that mood disorders, anxiety and other psychiatric co-morbidities increase the suffering associated with pain, which has resulted in an increase in the use of non-opioid drugs such as antidepressants. Certain antidepressants have propensity to anticholinergic effects, vasomotor symptoms, weight gain, sexual dysfunction, emotional blunting and suicidality and need to be chosen carefully based on risk and co-morbidities.<sup>159</sup>

Breakthroughs in neuroscience regarding the roles of glial cells<sup>160</sup> and other pain modulating neuroplastic changes have led to the premature use of purported *modulators of glial function*, including ketamine, naltrexone, dextromethorphan, some tricyclics and other drugs, with variable results.<sup>161,162</sup> But an effective course of acupuncture applied to local points for carpal tunnel syndrome results in distinct neuroplastic changes.<sup>87,163</sup> as do other nonpharmacologic interventions for chronic pain.<sup>164</sup> This trend to include the neuroplastic related aspects of chronic pain represents a significant contribution to pain care and is the focus of further research.

*Topical medications* from various categories including local and general anesthetics (e.g., lidocaine and ketamine), muscle relaxants (e.g., baclofen), capsaicin, anti-inflammatory drugs (e.g., ketoprofen and diclofenac), and antidepressants (e.g., amitriptyline) are used singularly or in combination for local pain management. Anti-inflammatories and capsaicin have been most studied and have the strongest evidence for benefit in musculoskeletal and neuropathic pain, respectively.<sup>165,166</sup> Local anesthetics have been used topically and as intralesional injections. More recently intravenous infusions have been used for neuropathic pain or generalized pain.<sup>167</sup>

Inhaled and topical medications containing *cannabinoids*, most commonly tetrahydrocannabinol (THC) and the less psychotropic cannabidiol (CBD), interact with

cannabinoid receptors primarily in the brain to provide a broad range of effects.<sup>168</sup> In addition to reduction of nausea, recent evidence demonstrates that cannabinoids exhibit comparable effectiveness to opioids in models of acute pain and significant effectiveness in chronic neuropathic pain.<sup>169,170</sup> In a systematic review of RCTs of medical marijuana for CNCP, no serious adverse events were noted but “neurocognitive adverse effects related to learning, memory, and psychomotor deficits were common even with low-dose, short-term use of medical marijuana though they appear well tolerated”.<sup>171</sup> Headaches, sedation, dysphoria, and poor concentration were also noted. Long-term consequences of medical marijuana remain unknown and research is ongoing for benefit in non-neuropathic chronic pain.

Several classes of condition-based medications like *triptans* are prescribed for acute migraine<sup>172</sup> and ‘disease modifying agents’ in autoimmune conditions have benefit in reducing pain related to these conditions, as in rheumatoid arthritis.<sup>173</sup> Cardiovascular and immunosuppressive adverse effects limit their use.

## Imaging, procedures and surgery

In medical systems where a team approach to care is absent, a variety of specialists end up delivering a menu of very similar services, primarily medication, along with costly, invasive procedures and surgeries. A sometimes-premature response to or over-interpretation of imaging technology can result in higher rates of procedures and surgeries.

In the first decade of the 21<sup>st</sup> century, the use of high-cost imaging for the spine and joints for pain rose dramatically.<sup>174</sup> However, studies suggest that MRI findings do not correlate well with pain intensity or functional impairment, nor is advanced imaging associated with better outcomes.<sup>175</sup> Surgery rates are highest in areas of the country where imaging rates are highest,<sup>176</sup> yet imaging is not associated with an advantage in subsequent pain, function, quality of life or overall improvement.<sup>35</sup> While the process of imaging is not related to a high incidence of adverse events, part of the risk of imaging is the prompting of interventions that may result in increased risk with little gain. Moreover, common age-related, nonspecific MRI findings such as degenerative disc disease or anomalies of the spine may unnecessarily contribute to patient alarm and distress<sup>35</sup> that leads to reduced physical and work activity and a vicious cycle of disuse, distress, and greater disability. The focus on imaging encourages patients to identify with their anatomical pathology often with little understanding of how that contributed to their pain or functional state.

Procedures for pain include injections of various kinds, nerve blocks, epidurals, tissue ablations, spinal cord stimulators and pain pumps. These procedures can significantly reduce suffering and allow salvage of damaged limbs and tissues in the case of acute tissue injury. Timely use of these techniques can reduce the development of post-traumatic stress disorder (PTSD).<sup>177</sup> In chronic pain these interventions can also be very helpful in carefully selected patients.<sup>178,179</sup> Unfortunately, for many procedures there are no practice guidelines that are universally followed. Expensive interventional procedures for chronic pain, such as epidural and joint steroid injections increased by 228% from 2000 to 2011,<sup>180</sup> and surgical center utilization

increased by 300%.<sup>181</sup> The overuse of these strategies raises risk for patients and costs to the system. Moreover, their lack of effectiveness can be demoralizing for patients.<sup>182,183</sup>

As the long-term outcomes of surgical procedures are assessed, it is more evident that surgery performed to alleviate pain often does not achieve its goal. In geographic regions, the best spinal surgery outcomes occurred where surgery rates were the lowest; the worst results occurred in areas where rates were the highest.<sup>35</sup> Structural pathology of the knee, rated during meniscal surgery, for example, does not correlate with patient reported pain and function.<sup>184</sup> There is equivocal evidence for many common surgeries intended to remedy chronic pain; knee arthroscopies<sup>185</sup> and meniscectomies, for example.<sup>186-188</sup> Surgery is found effective in the short but not in the long term for most patients with cervical radiculopathy and facet arthropathy neck pain.<sup>189</sup> When long-term follow-up for lumbar spine stenosis surgery is done, non-operative groups fare as well as the operative groups,<sup>190</sup> except the operative groups experience an increased rate of side effects.

The cost of a laminectomy can range from \$50,000 to \$90,000 without insurance and up to \$2000 in copayments with insurance coverage. A spinal fusion can cost between \$80,000-\$150,000.<sup>191</sup> “Despite no specific concurrent reports of clarified indications or improved efficacy, there was a 220% increase in the rate of lumbar spine fusion surgery from 1990 to 2001 in the US.”<sup>35</sup> Yet there are no clear benefits observed with surgical versus non-surgical treatment.<sup>190</sup> Conservative treatment including physical therapy has been associated with positive long-term outcome and a reduced likelihood of cross-over to surgery after one year.<sup>192</sup>

Increased costs and lack of evidence of efficacy is not to condemn surgery as an option, but to question practice that engages surgery before or instead of more conservative, evidence-based therapeutic care. Decisions are complicated by a business model of medicine that continues to value costly interventions not necessarily supported by evidence, particularly in the case of chronic pain and despite the fact that many patients who submit to surgery do not have resolution of their chronic pain.

While more research is needed to understand the progression from acute to chronic pain, it is clear that the limited, siloed strategies of the prevalent pain management system have not addressed the scope of pain in America. The NIH National Pain Strategy,<sup>4</sup> NAM,<sup>82</sup> the CDC opioid guidelines,<sup>193</sup> the updated pain mandate from The Joint Commission,<sup>194</sup> the FDA,<sup>195</sup> and the American College of Physicians (ACP) Clinical Practice Guideline (ACP)<sup>196</sup> recommend evidence-informed, comprehensive pain care while conceding that past strategies generally, and the use of opioid medications specifically, have not remedied but rather exacerbated chronic pain, abuse, addiction, illness behavior and disability. Rapidly emerging science continues to inform our understanding of pain states and potential responses. Emerging science about the impact on pain states by the microbiome,<sup>197-199</sup> mitochondria,<sup>200</sup> fascia,<sup>201-203</sup> glia<sup>160</sup> and neuroplasticity,<sup>87,163</sup> and movement disorders secondary to pain<sup>86</sup> will likely inform future pain treatments.

The national pain strategies are shifting from a model of pain care, well-intentioned but delivered in specialty silos, favoring expensive solutions that have equivocal evidence of benefit

to multimodal evidence-informed options, fitted to a patient's whole experience of pain and therapeutic goals.

Evidence-informed practice is based in evaluation and dissemination of current research including biological, medical and behavioral science. Thirty seven US State Attorneys General have submitted a letter to America's Health Insurance Plans (AHIP) asking them to include and incentivize evidence-based nonopioid treatments for pain.<sup>204</sup> Nonpharmacologic therapies for pain are now recommended by the American College of Physicians (ACP) for acute and chronic low back pain. As of January 1, 2018, the largest hospital accreditation organization, the Joint Commission, will require hospitals provide nonpharmacologic modalities for pain.<sup>204</sup> The current evidence for nonpharmacologic therapies for acute and chronic pain is detailed next.

## **SECTION 2 - SOLUTIONS TO THE PROBLEM**

### **EVIDENCE-BASED NONPHARMACOLOGIC PAIN CARE (NPPC)**

Nonpharmacologic therapies are best considered within the context of all evidence-based medical treatment. The terms 'complementary and alternative' stratify care by considerations other than evidence of effectiveness and risk. Evidence-based nonpharmacologic therapies are safe and effective components in comprehensive pain care that can also be opioid sparing, that is, reduce the need for opioids to manage severe, acute pain and consequently reduce the need for chronic opioids. Nonpharmacologic therapies can be stand-alone interventions or work in combination with medicine, procedures or surgery. An often underrecognized feature of nonpharmacologic therapies is their ability to confer additional benefits: a treatment to reduce pain can also reduce anxiety and depression, nausea and vomiting; facilitate restful sleep; and increase a patient's sense of well-being and desire to participate in their own recovery.

Policy decisions for strategies on pain care must be informed by research and evidence for all practices in medicine. The assumption that conventional care is proven care has been challenged by reviews: the U.S Office of Technology Assessment in 1978 estimated that only 10-20% of all procedures then used in medical practice were shown to be efficacious by controlled trial.<sup>205</sup> Estimates reported in the early 1990's determined 10-15% of medical interventions were based on results from randomized controlled trials; by 2003 that figure improved: approximately 50%, of conventional care was found to be evidence-based.<sup>206</sup> Comprehensive, research-informed care should follow the evidence and include all evidence-based disciplines in a multimodal approach to pain care, particularly therapies that have evidence not only in the short term but have been evaluated for impact longitudinally, that is, care that registers improvement months and years following a course of treatment.<sup>207,208</sup>

There are effective nonpharmacologic therapies available from licensed and regulated professionals such as acupuncture therapy, massage therapy, osteopathic manual medicine, chiropractic, physical therapy, and psychology. There are instructors trained in evidence-based, directed or self-engaged movement and meditative movement therapies as in yoga and Tai chi.

Lifestyle or behavioral approaches, such as stress management, cognitive behavioral therapy, meditation/mindfulness, and meditative movement therapies are also recommended as nonpharmacologic strategies. Other lifestyle approaches including diet and sleep hygiene have been shown to benefit health. These are low risk, low cost, well accepted by patients and many have been used successfully for thousands of years.

There is an additional benefit to many of NPPC strategies; unlike drugs and surgery, they involve patient participation and a commitment to self-care. Increased self-efficacy in managing pain often accompanies NPPC and correlates with improved mood and predicts improved outcomes in many chronic conditions, including pain.<sup>209</sup> For example, the military has studied “active self-care therapies” as a category of pain management that may be of value in an integrated, multimodal approach.<sup>210</sup>

## **Evidence-Based Nonpharmacologic Therapies for Acute Pain**

Over 50% of chronic opioid use begins in the acute care setting, after surgery, or for treatment of acute injury related pain.<sup>129</sup> Nonpharmacologic therapies have demonstrated benefit for acute pain with opioid sparing in hospital settings for inpatient post-operative pain and for acute pain not related to surgery. The largest hospital accreditation organization in the US, The Joint Commission (TJC), has revised their pain mandate that was introduced in 2000. Effective January 1, 2018, TJC will require that their accredited hospitals and facilities ‘provide’ nonpharmacologic therapies for pain as a ‘scorable’ Element of Performance.<sup>194</sup> Per TJC clarification statement of 2015, these include but are not limited to, physical modalities such as acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, physical therapy (PT), relaxation therapy, and cognitive behavioral therapy (CBT). While CBT, PT, exercise<sup>2</sup> and electrical stimulation (E-Stim) have shown benefit for chronic pain,<sup>211,212</sup> they are not detailed in this evidence review as they are currently recognized and part of covered conventional care options, albeit underutilized in some systems. CBT, PT, exercise and E-Stim are recognized nonpharmacologic therapies for pain and included in the recommendations.

## **Nonpharmacologic Therapies for Acute Inpatient Pain with Opioid Sparing**

### ***Acupuncture therapy post-operative pain***

Acupuncture is understood as the insertion and manipulation of fine solid core needles at specified points or combination of points on the body. ‘Acupuncture therapy’ derives from the traditional East Asian paradigm recognizing the interrelationship of organs and body points and channels as well as associated symptoms, disease and dysfunction. Depending on a state’s scope of practice, acupuncture often includes treating by means of mechanical, thermal or electrical stimulation; by insertion of needles, or by application of heat, pressure, or other forms of

stimulation. In practice, acupuncture needling is often done in combination with other therapies such as palpation, Tui na, Gua sha, cupping, moxibustion, e-stim, auricular treatment, herbal medicine and recommendations on diet, exercise, self-reflection and meditative movement like Tai chi. Acupuncture therapy, therefore includes acupuncture needling, accompanying therapies and recommendations that engage a patient in self-care, particularly in the treatment of chronic pain.

In multiple systematic reviews with meta-analyses, acupuncture was effective in reducing post-surgical pain compared to sham acupuncture, controls and usual care with reduction in opioid need (21% opioid reduction at 8 hours, 23% at 24 hours and 29 % at 72 hours post-surgery) with lowered incidence of opioid-related side effects such as nausea, dizziness, sedation, pruritus and urinary retention.<sup>213-215</sup> A systematic review with meta-analysis found acupuncture after total knee arthroplasty reduced pain and was associated with delayed opioid use.<sup>216</sup> In a systematic review and meta-analysis, peri-operative auricular acupuncture reduced postoperative pain and need for analgesic use compared to sham or standard-of-care controls.<sup>217</sup> Pain benefit at 48 hours was equivalent to analgesics with fewer side effects. These findings have potential for reduction in hospital readmission due to uncontrolled pain.<sup>218</sup>

Intraoperative electrical stimulation of acupuncture points reduced intraoperative opioid requirements, post-operative pain and duration of stay in the post anesthesia care unit.<sup>219</sup> Acupuncture was effective, safe, and well tolerated for post-tonsillectomy pain in children with no significant side effects.<sup>220</sup> The American Pain Society's guidelines on post-operative pain management neither 'recommend nor discourage' acupuncture therapy as part of recommended multimodal post-operative pain based on the literature available at the time of their guideline writing.<sup>221</sup> A subsequent systematic review with meta-analysis cited above supports the use of acupuncture as adjuvant therapy in treating postoperative pain and reducing opioid use.<sup>214</sup>

### ***Acupuncture therapy acute non-surgical pain***

For acute and subacute low back pain, a systematic review with meta-analysis<sup>222</sup> led the American College of Physicians (ACP) to recommend acupuncture as a first-line of care.<sup>141</sup> Acupuncture is also effective for acute migraine.<sup>223</sup> In an RCT enrolling 300 patients with acute pain presenting to an emergency department, acupuncture was superior to parenteral morphine for pain relief and onset of action with fewer adverse effects.<sup>224</sup> A retrospective study of emergency department acute pain patients found acupuncture decreased pain comparable to analgesics with additional benefit of reduction in anxiety.<sup>225</sup> A trial of 1964 patients found acupuncture benefit comparable to pharmacotherapy for emergency department patients presenting with acute low back pain and ankle sprain.<sup>226</sup> A systematic review with meta-analysis of acupuncture analgesia in the emergency setting found acupuncture '...provided statistically significant, clinically meaningful and improved levels of patient satisfaction with respect to pain relief in the emergency setting'.<sup>227</sup> The authors found evidence of lower cost and low adverse effects profile. In an observational study of 1008 patients including children, acupuncture given

as first aid immediately after, optimally within 48 hours, of a burn injury reduced pain, reddening, pigmentation, scarring and PTSD that commonly follows traumatic burns.<sup>228</sup>

### **Acupuncture therapy safety**

Acupuncture has a ‘relative risk’ that is low. The NIH Consensus Statement on Acupuncture published in 1998 found that ‘the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions.’<sup>229</sup> Systematic reviews and surveys have clarified that acupuncture is safe when performed by appropriately trained practitioners<sup>230-237</sup> with infrequent minor side effects such as feeling relaxed, elated, tired or having sensation or itching at point of insertion.<sup>234</sup> Rare serious complications such as infection or pneumothorax are directly related to insufficient training.<sup>235,236,238</sup> Safe use of acupuncture has also been established in pediatrics<sup>230,239-241</sup> and for women who are pregnant.<sup>242-244</sup>

### **Massage therapy post-operative pain**

Massage therapy involves manipulation of soft tissue structures of the body to prevent or alleviate pain, spasm, tension, or stress and to promote health and wellness. A systematic review with meta-analysis of 10 trials showed a single dose of massage therapy provided significant improvement in post-operative pain.<sup>245</sup> In a systematic review of 16 trials, massage therapy was effective for treating pain and anxiety compared to active comparators in surgical pain populations.<sup>246</sup> In a randomized trial of veterans undergoing major surgery, massage was effective and a safe adjuvant therapy for the relief of acute post-operative pain.<sup>247</sup> Massage is effective for pain reduction in post-cesarean section patients,<sup>248</sup> cardiac,<sup>249</sup> and thoracic surgery patients.<sup>250</sup>

### **Massage therapy safety**

Therapeutic massage is relatively safe. Studies in adults and children with cancer<sup>251-253</sup> and in the post-operative period<sup>247</sup> have found rare serious adverse events<sup>254-256</sup> and low rates of minor complaints such as muscle soreness.<sup>141</sup>

## ***Mind body<sup>1</sup> directed therapies post-operative and acute pain***

### ***Music therapy post-operative acute pain***

A systematic review with meta-analysis of research found music therapy reduced pain in burn patients<sup>257</sup> and in pediatric post-operative pain.<sup>258</sup> A meta-analysis of 97 studies evaluating music therapies for pain from a variety of causes (acute and procedural pain, and cancer/chronic pain) demonstrated statistically significant decreases in pain intensity, emotional distress, and analgesic use, both opioid and non-opioid intake.<sup>259</sup> A trial of music therapy for post-cesarean section pain found decreased pain in the 24 hours following surgery and decreased analgesic consumption in the first four hours.<sup>260</sup>

### ***Suggestive techniques and guided imagery post-operative and acute pain***

A meta-analysis of trials found suggestive techniques such as hypnosis may be useful tools to alleviate post-operative pain, especially in minor surgeries.<sup>261</sup> A systematic review and meta-analysis of the efficacy of audio recorded therapeutic suggestions given while under general anesthesia found no effect on pain and small but significant effects on medication use and recovery.<sup>262</sup> Listening to a guided imagery CD 2 weeks before and 3 weeks after total knee replacement resulted in reduced pain that persisted at 3 weeks.<sup>263</sup>

### ***Virtual reality assisted distraction***

Virtual reality (VR) technology enables people to become immersed in a computer-simulated, three-dimensional environment as a distraction to pain.<sup>264</sup> Coupled with standard analgesia, VR has been found beneficial in reduction of burn-induced pain and burn wound care in adults and children.<sup>264,265</sup> VR assisted burn and nonburn wound care reduced opioid need by 39% compared to no VR, while levels of pain and anxiety were similar.<sup>266</sup> VR has shown potential in inpatient cancer procedure-related pain.<sup>267</sup>

## **Mind body directed therapies safety**

Music therapy, suggestive techniques, and guided imagery are not associated with significant adverse effects and are safe options to improve post-operative recovery.<sup>260-262</sup> VR has

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<sup>1</sup> The term ‘mind body’ represents an attempt to accommodate the bidirectional or circular impact that interventions have on symptoms typically categorized as either mental/psychological/spiritual or ‘discretely physical’. However, this is an artificial bifurcation since all body systems use identical communication molecules and mechanisms and since there is never a physical condition that does not register a psychological component. We use the term here as it has been utilized in the current literature but acknowledge a certain limitation shared by terms such as ‘behavioral’ or ‘relaxation’ therapies.

potential risk of nausea and increased potential for collisions with objects in the real world.<sup>268</sup> The latter is controlled by creating ‘safe areas’ to use VR and with in-person ‘spotting’ supervision. Debriefing post-VR experience may benefit especially young children and those vulnerable to effects of immersive reality experience.

## **Multimodal approach to acute pain care**

Multimodal pain care is now recognized as the optimal inclusive and responsive approach to patients experiencing pain: inclusive of all evidence-based therapies including effective nonpharmacologic options and responsive to patient’s diverse and evolving needs. Evidence-based nonpharmacologic therapies are recommended in comprehensive pediatric and adult pain care.<sup>82,194,269</sup> Multimodal pain care is recommended by the American Pain Society in their guidelines to post-operative pain management.<sup>221</sup> Effective nonpharmacologic options are recommended by the ACP in their guidelines for acute low back pain.<sup>141</sup>

## **Frequency, dosage and timing of nonpharmacologic interventions for inpatient and acute pain care**

Therapies that are delivered by a single licensed independent practitioner, such as an acupuncturist, massage therapist or therapist providing an engaged or guided mind/body intervention, are generally given as daily treatment for the term of the inpatient stay with referral for outpatient care follow-up. Care such as music therapy or virtual guided imagery are not single practitioner dependent. Access can be continuous or timed if provided by recordings that can be self-administered by patients. A session of inpatient acupuncture or massage therapy care can last from 20-45 minutes. There is evidence-based data on dosage and frequency of nonpharmacologic therapies, but more research is needed to determine the optimal frequency, dosage and timing of interventions: length of a session, or for the case of acupuncture therapy, what constitutes an optimal intervention in terms of session time, number of points palpated, needed, point retention time, and with what additional hands-on therapies.

## **Evidence-Based Nonpharmacologic Therapies for Cancer Pain**

### ***Acupuncture therapy cancer pain***

The American Society of Clinical Oncology Clinical Practice Guidelines found acupuncture was effective in improving pain. The reviewers categorized these findings as ‘evidence-based; benefits outweigh harms; evidence quality: low; strength of recommendation: weak’.<sup>270</sup> A more recent systematic review with meta-analysis of 29 RCTs found acupuncture effective for cancer-related pain, particularly malignancy-related and surgery-induced pain.<sup>75</sup> Acupuncture alleviates side effects of oncology radiation, including pain associated dysphagia,<sup>271</sup>

as was found in a systematic review of acupuncture treatment for dysphagia following stroke.<sup>272</sup> Cancer patients receiving inpatient acupuncture at a major cancer center experienced significant improvement in pain, sleep disturbance, anxiety, drowsiness, nausea, and fatigue.<sup>273</sup> In a systematic review with meta-analysis acupuncture relieved joint pain associated with breast cancer treatment induced menopause.<sup>274</sup> A review on the management of peripheral neuropathy induced by chemotherapy found acupuncture to be among therapies that may be useful.<sup>275</sup>

### ***Massage therapy cancer pain***

Massage therapy was found in systematic reviews with meta-analyses to be effective for pain in cancer patients compared to active comparators<sup>276</sup> or usual care.<sup>76</sup> Massage therapy was also effective for metastatic bone pain,<sup>277</sup> for pain in children with cancer<sup>278</sup> and those undergoing stem cell transplantation.<sup>278,279</sup>

### ***Mind body directed therapy cancer pain***

Mindfulness-based courses including web-based mindfulness interventions (eHealth)<sup>280</sup> are supportive for cancer patient's symptom burden. In systematic reviews with meta-analyses Mindfulness-Based Stress Reduction (MBSR) had a beneficial psychological impact for breast cancer patients,<sup>281,282</sup> and on quality of life, mood and distress in cancer patients.<sup>283</sup> A recent trial of MBSR for metastatic breast cancer patients demonstrated a positive impact on distress with a mild effect of improving average pain.<sup>284</sup>

In a large systematic review with meta-analysis, music therapy showed statistical improvements in cancer pain, emotional distress from pain and a small but statistical effect on anesthetic use, opioid and non-opioid intake.<sup>259</sup> Music therapy in a palliative care setting found significant improvement in pain, anxiety, depression, shortness of breath and mood.<sup>77</sup>

## **Evidence-Based Nonpharmacologic Therapies for Chronic Pain**

Nonpharmacologic therapies are well studied and effective for chronic pain. A Clinical Practice Guideline from the American College of Physicians (ACP) states nonpharmacologic interventions should be considered as first-line options in chronic low back pain, noting that fewer harms are associated with these effective therapies than with pharmacologic options. The ACP emphasizes therapies be administered by practitioners with appropriate training.<sup>141</sup>

### ***Acupuncture therapy chronic pain***

Acupuncture has accrued the most evidence in the treatment of chronic pain. An individual patient data meta-analysis of 29 randomized trials involving 17,922 patients using acupuncture therapy for chronic musculoskeletal pain related to the neck and low back, knee OA,

headache and migraine found acupuncture was significantly better than both sham acupuncture and usual care for all conditions.<sup>285,286</sup> In a systematic review with meta-analysis, acupuncture was associated with greater, immediate relief of chronic pain compared to sham acupuncture or analgesic injection.<sup>287</sup> In a meta-analysis on long term impact, the effects of a course of acupuncture treatment for patients with chronic pain persisted significantly following care; 90% of acupuncture benefit persisted at 12 months in trials using wait list or usual care controls. Trials comparing acupuncture to sham found 50% persistence of benefit at 12 months for the verum groups.<sup>208</sup>

An updated individual patient meta-analysis of acupuncture for chronic nonspecific back pain, neck pain, shoulder pain, chronic headache or osteoarthritis included an additional 7 years of trials evaluating 39 trials (20,827 patients).<sup>288</sup> Acupuncture was superior to both sham and no acupuncture controls for each pain condition. The effects of acupuncture were found to persist over time with only a small decrease, approximately 15%, in treatment effect at one year after randomization or 9-10 months after the completion of treatment. A novel finding was additional confirmation of benefit for acupuncture over sham on upper body musculoskeletal pain, neck and shoulder pain.

In a systematic review with meta-analysis, acupuncture showed benefit over controls in the treatment of peripheral neuropathy related to diabetes, HIV, Bell's palsy and carpal tunnel syndrome.<sup>289</sup> Simple pressure sustained by seeds or small magnets taped to ear points, a form of auricular treatment, showed benefit in acute and chronic pain in systematic reviews with meta-analysis.<sup>217,290</sup>

In a large multicenter trial of 14,161 patients with chronic neck pain, acupuncture (15 sessions over 3 months) added to routine care was associated with improvements in neck pain and disability maintained through 6 months compared to routine care alone.<sup>291</sup> Although acupuncture care increased cost of treatment, the health benefits lasted well beyond the three-month study duration; per international cost-effectiveness threshold values, acupuncture was determined to be a cost-effective treatment strategy.<sup>292</sup> In a cost-effectiveness review of nonpharmacologic interventions for low back pain (LBP), acupuncture was found to be a cost-effective option.<sup>211</sup> Meta-analyses demonstrate acupuncture is effective and cost-effective for knee OA.<sup>293,294</sup> A systematic review and meta-analysis of manual acupuncture for myofascial pain syndrome found treatment of myofascial trigger points reduced pain and improved pain threshold in studies using a single treatment or a course of 8 treatments.<sup>295</sup> Further research is needed to clarify the longitudinal impact of myofascial trigger point treatments as single or multiple sessions. A network meta-analysis of acupuncture needling alone and combined with Gua sha, moxibustion, or e-stim are effective in decreasing pain and in improving physical function in myofascial pain syndrome.<sup>296</sup>

In systematic reviews<sup>297,298</sup> and meta-analyses,<sup>299</sup> acupuncture was found effective for frequent episodic or chronic tension headaches and for episodic migraine. Acupuncture has also been shown to be effective for chronic shoulder pain,<sup>285,300</sup> pain related to OA of the hip,<sup>301</sup> and temporomandibular disorder myofascial pain.<sup>302,303</sup> In a military population, acupuncture treatment given at least 4 times within a year was associated with improved symptoms, ability to

function and sense of wellbeing as well as reductions in opioid prescriptions (45%) muscle relaxants (34%), NSAIDs (42 %) and benzodiazepines (14%).<sup>304</sup>

In a systematic review and meta-analysis, acupuncture therapies with prokinetics were more effective than prokinetics alone for functional dyspepsia.<sup>305</sup> Acupuncture therapy is recommended for functional dyspepsia in patients contraindicated for prokinetics.

A systematic review and meta-analysis of trials comparing acupoint stimulation to NSAIDs for primary dysmenorrhea found advantages in acupoint stimulation in alleviation of dysmenorrhea symptoms with fewer side effects and potential use for patients with NSAID contraindication.<sup>306</sup>

Based on their systematic review, the American College of Physicians (ACP) Clinical Practice Guideline recommends acupuncture for acute, subacute and chronic low back pain (cLBP).<sup>141,222</sup> The US Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ) concluded that acupuncture therapy is effective for cLBP compared to placebo, sham, no treatment, usual care, or wait list controls.<sup>145</sup> The NIH also recommends acupuncture for low back pain and for knee OA.<sup>307</sup> The *FDA Education Blueprint For Health care Providers Involved In The Management or Support of Patients with Pain* suggests acupuncture among a range of available therapies as part of a multidisciplinary approach to pain management.<sup>195</sup>

As stated above, acupuncture therapy has a ‘relative risk’ that is low when provided by qualified trained practitioners.

### **Massage therapy chronic pain**

Based on their systematic review, the ACP Clinical Practice Guideline recommends massage for acute, subacute and chronic low back pain (cLBP).<sup>141,222</sup> AHRQ found massage effective for cLBP compared to placebo, sham, no treatment, usual care, or wait list controls.<sup>145</sup> The NIH also recommends massage for neck pain.<sup>307</sup>

Sixty high quality and seven low quality studies included in a systematic review with meta-analysis on pain and function across all pain populations found massage therapy effectively treats pain compared to sham, no treatment, and active comparators.<sup>308</sup> A systematic review for upper and lower extremity conditions found soft tissue therapy effective for the management of heel pain and lateral epicondylitis.<sup>309</sup> A trial of massage therapy for knee OA found the optimal dose at 8 weekly one-hour sessions with benefits persisting for at least 8 weeks beyond treatment.<sup>310</sup> A systematic review with meta-analysis found manual therapy including massage was effective for pain, stiffness and physical function in knee OA with a call for more study with extended follow-up.<sup>311</sup> Stiffness and physical function showed significant improvement with treatment duration of more than 4 weeks.

As indicated above, massage therapy has a low risk of adverse events when provided by a trained practitioner.

## ***Spinal manipulation therapy and manipulative therapy chronic pain***

Spinal manipulative therapy (SMT) involves treatment of the spine and pelvic related joints; manipulative therapy (MT) refers to the treatment of other joints in the body including upper and lower extremities. SMT and MT are often associated with high velocity, low amplitude (HVLA) thrust techniques, as well as low velocity, low amplitude (LVLA) or joint mobilization techniques. SMT, MT, HVLA and LVLA are techniques commonly used to improve pain and function, primarily by osteopathic physicians and chiropractors.

A systematic review with meta-analysis showed SMT improves low back pain with benefits maintained for up to 6 weeks.<sup>312</sup> SMT was also shown to be cost-effective for low back pain.<sup>211</sup> Based on their systematic review, the ACP Clinical Practice Guideline recommends spinal manipulation for acute, subacute and chronic low back pain (cLBP).<sup>141,222</sup> AHRQ found SMT as effective as other active interventions for cLBP).<sup>145</sup> Systematic reviews found SMT beneficial for neck pain,<sup>313</sup> cervicogenic headache,<sup>314</sup> and prophylaxis of migraine.<sup>315</sup>

Systematic reviews and a meta-analyses found manual therapy beneficial for knee OA<sup>311,316</sup> as well as OA of the hip, patellofemoral syndrome, ankle inversion sprain, plantar fasciitis<sup>317</sup> and common shoulder disorders.<sup>318</sup> A systematic review also found evidence that MT is effective when combined with exercise and/or multimodal therapy for lateral epicondylitis, carpal tunnel syndrome and temporomandibular disorders.<sup>319</sup> A systematic review found for adults with ‘whiplash-associated disorders’ and ‘neck pain associated disorders’, nonpharmacologic therapies including manual therapy are cost-effective.<sup>320</sup> For improving low back and shoulder pain, MT may be more cost-effective than usual care that included exercise, stabilization and/or advice about activity.<sup>321</sup>

### **Manipulation therapy safety**

Adverse events associated with spinal manipulation include muscle soreness or transient increases in pain.<sup>141</sup> Rare serious adverse events include cervical artery dissection, stroke and neck injury.<sup>322</sup> The most recent review of systematic reviews confirms that though rare, there is some risk of significant adverse events.<sup>323</sup>

## **Mind body directed therapies for chronic pain**

### ***Mindfulness, meditation and relaxation therapies chronic pain***

Mindfulness and meditation-based therapies focus training on moment to moment awareness of breathing and attention without judgment to transform perception and relationships to pain and the larger environment.

Mindfulness-based stress reduction (MBSR) is a training that has had considerable study for chronic pain. A systematic review and meta-analysis found MBSR for low back pain was associated with short-term improvements in pain intensity and physical functioning compared to

usual care.<sup>324</sup> In a trial for patients with chronic low back pain, comparing MBSR to CBT or usual care found both MBSR and CBT to be cost-effective and MBSR to be cost-saving.<sup>212</sup> CBT is recognized as a moderately effective approach to chronic pain, for example, low back pain;<sup>141</sup> however, we do not include an in-depth review of CBT as it is currently part of covered conventional care options, albeit underutilized. Based on their systematic review, the American College of Physicians (ACP) Clinical Practice Guideline recommend CBT and MBSR for chronic low back pain.<sup>141,222</sup>

Mindfulness and relaxation-based eHealth interventions have evidence of positive effects on health outcomes for patients with chronic pain including headache, fibromyalgia, and irritable bowel syndrome.<sup>280</sup> Internet-delivered pain-coping skills training (PCST) with physiotherapist-prescribed home exercise for persons with chronic knee pain provided clinically meaningful improvements in pain and function that are sustained for at least 6 months.<sup>325</sup> PCST is an approach based on CBT principles that target psychological factors such as low self-efficacy, poor pain coping, and pain catastrophizing, common in persons with chronic pain. PCST has been shown to be effective for osteoarthritis or rheumatoid arthritis pain,<sup>326</sup> and specifically knee OA.<sup>327</sup>

MBSR has also shown benefit in adolescent pain<sup>328,329</sup> and adult patients with chronic headache.<sup>330,331</sup> A review of patients with arthritis, chronic back or neck pain, or two or more comorbid pain conditions experienced the largest average improvement from a mindfulness program in pain severity and functional limitations.<sup>332</sup> Greater home meditation practice was significantly associated with greater improvements in psychological distress and self-rated general health. Benefit for pain and high continued compliance have been consistently associated with MBSR from its earliest study.<sup>333</sup>

Relaxation therapies use physiologic techniques (e.g., slow diaphragmatic breathing, progressive muscle relaxation) that regulate the sympathetic/parasympathetic balance to reduce symptoms of sympathetic arousal often seen in chronic pain including situational stress, muscle tension and shallow breathing. They also include other directed therapies like guided imagery (use of words depicting calming images and music to evoke positive imaginative scenarios), hypnosis and suggestion (induction of a relaxed but focused state of consciousness receptive to positive suggestion), acceptance and commitment therapy (ACT) (strategies of mindful awareness and acceptance) and music therapy.

In a large meta-analysis, music therapy showed a reduction of chronic pain, emotional distress due to pain, and a small but statistically significant reduction in opioid and non-opioid intake.<sup>259</sup> Based on their systematic review, the ACP Clinical Practice Guideline recommends progressive relaxation for chronic low back pain.<sup>141,222</sup> The NIH also recommends relaxation, ‘autonomic regulatory’ approaches for fibromyalgia.<sup>307</sup>

In a meta-analysis of trials, acceptance and commitment therapy (ACT) and mindfulness-based interventions were shown to be comparable to cognitive behavioral therapy (CBT) in managing chronic pain.<sup>334</sup> ACT was comparable to CBT but with higher patient satisfaction in

one trial on chronic pain;<sup>335</sup> older adults with chronic pain were more likely to respond to ACT in another RCT.<sup>336</sup>

Systematic reviews of guided imagery were found encouraging but inconclusive for musculoskeletal and non-musculoskeletal pain.<sup>337,338</sup> A more recent systematic review of guided imagery in fibromyalgia, arthritis and rheumatologic disorders found statistically significant improvement in pain and function, with several trials demonstrating reduction in medication use.<sup>339</sup>

### **Mindfulness, meditation and relaxation therapy safety**

The body of research evidence has shown mindfulness-based practices, hypnosis, suggestive therapies, guided imagery, CBT, ACT and progressive relaxation techniques are utilized across diverse patient populations. These approaches are safe, with rare adverse reactions in psychiatric patients, people with epilepsy or those who have suffered abuse or trauma where relaxation may trigger a rare paradoxical reaction.<sup>141,324,339,340</sup>

### **Biofeedback chronic pain**

Biofeedback utilizes techniques in which a signal generated by a device trains the patient to manipulate an aspect of their physiology not typically directed (e.g. heart rate variability, muscle tension) and provides a self-care tool for physiologic modulation. A meta-analysis of biofeedback for chronic low back pain (cLBP) found pain reduction, reduced depression, disability, and muscle tension, and improved coping.<sup>341</sup> Based on another systematic review, the (ACP) Clinical Practice Guideline recommends electromyography biofeedback for cLBP.<sup>141,222</sup>

A meta-analysis of trials also found biofeedback effective for tension headache with stable benefit over an average follow-up phase of 15 months. Biofeedback with relaxation therapy was most effective for children and adolescents with headache.<sup>342</sup> A meta-analysis of biofeedback for fibromyalgia found significant reduction of pain,<sup>343</sup> with less effect established in another systematic review due to variability of measures across trials.<sup>344</sup>

### **Biofeedback safety**

In a systematic review of trials for fatigue and cognition, neurofeedback (EEG biofeedback) and biofeedback were shown to be well-tolerated without major adverse effects.<sup>345</sup> Biofeedback has low risk of harms with rare side effects of headache, fatigue or sleep problems.<sup>343</sup> No adverse events are reported in a meta-analysis of biofeedback for chronic back pain.<sup>341</sup>

## Movement therapies for chronic pain

### *Yoga chronic pain*

Therapeutic yoga is the use of yoga to help people with health problems manage their health conditions and reduce their symptoms. Yoga originated in ancient India and has been adapted in the West. Yoga practice combines attention and meditation (dhyana), breathing (pranayama), and physical postures (asanas).

A Cochrane review of yoga for chronic nonspecific back pain found moderate supporting evidence of yoga compared to non-exercise controls resulted in small to moderate improvements in back-related function at three and six months and was comparable to exercise for chronic low back pain (cLBP).<sup>346</sup> Early intervention of ‘medical yoga’, group sessions of guided Kundalini yoga individualized to each medically screened patient with low back pain, was found to be cost-effective.<sup>211,347</sup> Based on their systematic review, the American College of Physicians (ACP) Clinical Practice Guideline recommends yoga for cLBP.<sup>141,222</sup> AHRQ found yoga effective for cLBP pain compared to placebo, sham, no treatment, usual care, or wait list.<sup>145</sup> NIH recommends yoga (hatha, Iyengar and viniyoga) for cLBP.<sup>307</sup>

In a systematic review and summary of reviews,<sup>348,349</sup> yoga was found to have beneficial effects in patients with pain. In addition to low back pain, systematic reviews with meta-analysis found yoga beneficial for osteoarthritis, rheumatoid arthritis, kyphosis and fibromyalgia;<sup>350</sup> Additional systematic reviews found yoga to have positive effects on pain and function in patients with knee OA<sup>351</sup> and neck pain.<sup>352</sup> A meta-analysis found yoga, even as a short-term intervention, could be effective for pain and associated disability.<sup>353</sup> A large systematic review (306 trials) identified 52 different yoga styles and techniques with the most common being hatha, Iyengar, Pranayama and integrated approaches to yoga therapy. There was no advantage to a particular style of yoga. The reviewers recommended the choice of yoga style be based on personal preference and availability.<sup>354</sup> In a systematic review with meta-analysis on efficacy and safety of meditative movement therapies (Qi gong, Tai chi and yoga) for fibromyalgia syndrome, yoga yielded significant effects on pain, fatigue, sleep, depression and health-related quality of life at final treatment, while Tai chi showed benefit for sleep.<sup>355</sup> In an access-to-care innovation for veterans, a clinical yoga program via telehealth real-time interactive video conferencing, provided comparable satisfaction and health improvements to in-person yoga, including benefit for pain.<sup>356</sup>

### **Yoga therapy safety**

Reported harms associated with yoga for cLBP were mild to moderate,<sup>141,357</sup> self-limiting joint and back pain comparable to physical therapy (PT).<sup>358</sup> A systematic review and meta-analysis of RCTs found yoga to be as safe as usual care and exercise.<sup>359</sup> No association between yoga practice and joint problems was found in a large survey of women aged 62-67.<sup>360</sup> A review

of published adverse event cases associated with yoga recommends patients with medical preconditions such as glaucoma or compromised bone health work with physician and a qualified yoga teacher to adapt postures.<sup>361</sup>

### ***Tai chi chronic pain***

Tai chi is a low-impact, mind-body exercise originating in China that has become increasingly popular in the West as an effective exercise for rehabilitation related to multiple medical conditions. Tai chi consists of slow prescribed movements with attention to breathing and meditative concentration.

In systematic reviews with meta-analysis, Tai chi was effective for chronic pain associated with OA.<sup>362,363</sup> An evidence map of 107 systematic reviews on health outcomes confirmed its potential benefit for chronic pain syndromes and OA.<sup>364</sup> Based on their systematic review, the American College of Physicians (ACP) Clinical Practice Guideline recommends Tai chi for chronic low back pain (cLBP).<sup>141,222</sup> The US Department of Health and Human Services AHRQ found Tai chi effective for cLBP compared to placebo, sham, no treatment, usual care, or wait list controls.<sup>145</sup> The NIH also recommends Tai chi for knee OA and fibromyalgia.<sup>307</sup> In a RCT of 12 weeks of Tai chi with heart failure patients, decreased pain was among the physical benefits reported.<sup>365</sup>

### ***Tai chi safety***

In a review of 153 trials, adverse events related to Tai chi were not regularly monitored or reported. When reported, Tai chi did not result in any serious adverse events but was associated with minor musculoskeletal aches and pains not unlike other forms of therapeutic movement.<sup>366</sup>

### ***Other movement therapies chronic pain: Alexander technique, Pilates, and Feldenkrais***

Alexander technique (AT), Pilates, and Feldenkrais are therapies developed by Frederick Alexander, Joseph Pilates and Moshe Feldenkrais, respectively. They share features of touch, directed exercise, strengthening, and awareness of posture and muscle utilization in the treatment of pain and postural problems. While there are fewer studies and reviews of these therapies, there is evidence of benefit for chronic pain.

A systematic review supported the effectiveness of AT lessons in chronic back pain.<sup>367</sup> A large three-arm randomized trial compared usual care, usual care plus acupuncture therapy (10 sessions), and usual care plus AT (14 sessions) for chronic neck pain (median duration 6 years). The acupuncture and AT groups both led to significant reductions in pain and associated disability compared with usual care, with benefit persisting at 12 months following the intervention period.<sup>368</sup>

In systematic reviews of Pilates for chronic nonspecific low back pain, significant improvement in pain relief and functional enhancement was demonstrated.<sup>369</sup> Pilates exercise offered greater improvements in pain and functional ability compared to usual care and physical activity in the short term and improvements equivalent to massage therapy and other forms of exercise for chronic low back pain (cLBP) in the short or long term.<sup>370</sup> A trial of postmenopausal women with cLBP compared 6 weeks of Pilates plus physiotherapy to physiotherapy alone found improvement in pain management and functional status with benefits persisting after one year.<sup>371</sup>

Feldenkrais has demonstrated benefit in chronic pain trials for neck and scapular pain in people who are visually impaired.<sup>372</sup>

### **Alexander technique, Pilates, and Feldenkrais safety**

Adverse events related to movement therapies are low with minor events of transient pain and muscle soreness.<sup>368,373-375</sup>

## **Frequency, dosage and timing of nonpharmacologic interventions for chronic pain**

A recommended course of acupuncture treatment for chronic pain will depend on the patient and the term and severity of the condition. In a large meta-analysis of RCTs of acupuncture for chronic pain of the head, neck, shoulder, low back, and knee where benefit persisted significantly (12 months) following a course of treatment, patients received on average 8-15 treatments over 10-12 weeks.<sup>208</sup> In the Cochrane reviews recommending acupuncture for tension headache<sup>297</sup> and migraine,<sup>298</sup> a minimum of 6 sessions was required for review. Weekly treatment was common; no trials gave acupuncture more than twice per week.<sup>376</sup>

In a large meta-analysis that identified characteristics of acupuncture treatment associated with outcome, where average session time was recorded in a trial, the length of session averaged 16-45 minutes.<sup>376</sup> Average needle insertion sites were 6-20. Increased number of needle sites treated and more sessions were associated with better outcomes.<sup>376</sup> Therefore, referral for acupuncture therapy is recommended for at least 8 sessions, and preferably 8-15 weekly sessions of care. For a severe or acute ambulatory pain event, initial treatment frequency may be more than once per week.

Acupuncture therapy delivered in a group setting is being studied as an option for underserved populations,<sup>377</sup> in line with research on group medical visits.<sup>378</sup> Costs are reduced for patients and session times approximate individual practitioner-patient encounters. Patients' arrivals are staggered with care overlapping in a shared treatment space.

In a systematic review and meta-analysis of massage therapy for pain, treatment dosage ranged from a single session of 1.5 minutes to daily 40-60 minute sessions for 20 weeks.<sup>308</sup> In

chronic ambulatory pain conditions, massage is usually given once per week, more frequently for a severe or acute ambulatory event. Sessions are typically 45-60 minutes, longer if elected. Number of sessions recommended is not established in the literature.

Chiropractic and osteopathic spinal manipulation reviews include single sessions trials, trials of 4-7 session over 2 weeks to 5 months up to 12 sessions or more a month with or without subsequent maintenance.<sup>145</sup> Once a week sessions for 4-6 weeks was slightly superior to back school or physical therapy for chronic low back pain.<sup>379</sup>

The most studied mindfulness intervention is MBSR, which is structured as 8 weekly group sessions.<sup>222,324,380</sup>

Movement therapies like Tai chi and yoga are typically given in group session, and have been studied in a term of intervention from 1-5 sessions per week for 6 weeks to a year for Tai chi<sup>362,366</sup> and as 12 weekly sessions of 75 minutes for yoga.<sup>358</sup>

## **Lifestyle behaviors, self-efficacy chronic pain**

Self-efficacy is a psychological construct based on Social Cognitive Theory, which describes the interaction between behavioral, personal, and environmental factors in health and chronic disease. The theory proposes that patients' confidence in their ability to perform specific health behaviors influences their engagement in and actual performance of those behaviors, which in turn influences health outcomes.<sup>365</sup>

The evidence for the impact of healthy lifestyle choices—what we eat, drink, think, feel and do—on our health outcomes has become a major focus of current research. We are all born with a genome, a set of genes we inherit from our parents. Epigenetic changes happen when genes within our genome are turned on and off by environmental factors before and after conception. Epigenetic changes have been shown to be passed from generation to generation. Altered gene expression rather than genetic code accounts for the majority of risks to health outcomes. The NIH cites the following environmental factors as causes of epigenetic changes: exercise, diet, nicotine, alcohol, chemical exposures, medications and stress.<sup>381</sup> Though pain specific studies are scarce,<sup>382</sup> there are many studies that document the relationship of healthy behaviors to improved overall health and a reduction of disease, such as diabetes, atherosclerosis, and obesity,<sup>383</sup> that are associated with pain conditions.<sup>384,385</sup> The relationships are complex, multifactorial and have reciprocal influence on each other. For example, obesity is associated with inflammation<sup>386</sup> and musculoskeletal disorders involving connective tissue structures, including bones, joints and soft tissues of the musculoskeletal system.<sup>387,388</sup> At the same time, persistent or severe pain impedes weight loss in patients enrolled in weight management programs compared to none-to-moderate pain.<sup>389</sup> Poor blood sugar control in type II diabetes leads to delayed healing, neuropathic pain and vascular complications all of which increase the difficulties that patients have with exercise that can benefit diabetic control. Optimal lifestyle choices can improve health and pain and are tantamount to healthy outcomes.

Studies have shown that healthy life choices, such as dietary changes, self-engaged stress management, smoking cessation, exercise, and supportive relationships with others can impact depression, hypertension, heart disease, cholesterol, obesity, diabetes and prediabetes, and cancer.<sup>390,391</sup> Success with healthy lifestyle choices improves patient self-efficacy and is also found to improve the length of leukocyte telomeres,<sup>392</sup> associated with healthy aging and longevity.<sup>393,394</sup>

A large scale multiyear study, *The European Prospective Investigation Into Cancer and Nutrition–Potsdam Study* (EPIC), studied 23,000 people for 7.8 years to evaluate the impact of four lifestyle factors on health—never smoking, a BMI under 30, physical activity for at least 3.5 hours a week, and eating a healthy diet that includes vegetables, fruit, whole grain bread and low meat consumption.<sup>395</sup> Subjects with all four factors at baseline had reduced their risk of diabetes by 93%, myocardial infarction by 81%, strokes by 50%, and cancer by 36%, and had a 78% lower overall risk of developing a chronic disease. All of these diseases impact pain and healing. Lifestyle behaviors can affect biology as well as self-efficacy and therefore can be viewed as a key factor impacting pain.

## Nutrition and pain

Nutrition science is not new and though it has long been recognized that nutritional status can either promote or reduce body-wide inflammation<sup>396,397</sup> and can promote healing or inhibit it, most medical encounters for pain do not address diet in a meaningful way. As there is a growing awareness of the impact of nutritional status on overall health, there are more studies of nutrition and pain.<sup>398-400</sup>

An anti-inflammatory diet is one that is high in non-starchy vegetables, fruits, legumes, nuts and seeds, healthy oils and whole grains with low levels of animal protein consumption. This type of diet balances tissue pH levels for optimal mitochondrial enzyme functioning and has been shown to have health benefits.<sup>401</sup> Mitochondrial dysfunction in turn is being recognized as a root cause of many illnesses including pain related conditions.<sup>402-404</sup> Dietary antioxidants are essential for optimal mitochondrial health<sup>405</sup> and the basic science literature has thousands of articles on ‘targeting antioxidants to mitochondria’ within the last 10 years alone.<sup>406</sup>

Turmeric, its derivative curcumin, and ginger, a related tuber, are extensively studied in both food and supplement form for pain patients. Turmeric is used for a wide variety of painful and inflammatory conditions including peri-operative pain<sup>407</sup> with opioid and NSAID sparing; joint pain<sup>408-410</sup> and musculoskeletal pain;<sup>411</sup> and inflammatory bowel disease.<sup>412,413</sup> Ginger is studied for its effect on nausea<sup>414,415</sup> but also for pain,<sup>416-418</sup> including joint pain<sup>419</sup> and primary dysmenorrhea.<sup>420</sup> Though ginger and turmeric combine the actions of plant-based antioxidants and COX inhibition they are very well tolerated. Whereas pharmaceutical nonsteroidal anti-inflammatories (NSAIDs) cause very significant morbidity<sup>421,422</sup> and mortality,<sup>67</sup> ginger and turmeric do not show the same side effects profile.<sup>408,418,423</sup> This is likely, at least in part, because NSAIDs have been shown to inhibit the initial step in healing which is an inflammatory one.<sup>424</sup> A recent systematic review of curcuminoids for musculoskeletal pain found that in the studies

comparing curcuminoids to nonspecific NSAIDs, the evidence was moderate to high for non-inferiority of the curcuminoid intervention.<sup>411</sup> Curcuminoids were equal to NSAIDs in terms of pain improvement without the long-term risks related to morbidity and mortality of NSAIDs, situating curcuminoids as a viable oral pain medication option

Micronutrient deficiency is prevalent in the US,<sup>425</sup> associated with the extensive consumption of highly processed foods. Although consumption of meals from fast food restaurants is decreasing, there has been a compensatory increase in retail purchase of highly processed foods.<sup>426</sup> Symptoms associated with deficiencies, especially when sub-clinical, are nonspecific and include fatigue, irritability, aches and pains, decreased immune function and heart palpitations.<sup>425</sup> Supplementation of deficient nutrients helps overall health and is being studied for its effects on pain. The following is by no means a comprehensive listing, but touches on some of the most prevalent deficiencies.

Vitamin D is one of the best studied micronutrient deficiencies associated with pain and delayed healing. Skin pigmentation, obesity, northern latitudes and other yet unidentified factors lead to Vitamin D deficiencies. Deficiency of Vitamin D is often found in chronic pain sufferers, and is correlated with muscle fatigue risk factors.<sup>427</sup> While no definitive mechanism for how Vitamin D influences chronic pain development is known, supplementation of Vitamin D may benefit chronic pain.<sup>428</sup> It poses a low health risk, is well accepted, inexpensive and offers numerous health benefits.<sup>429</sup> A rapid dose of Vitamin D<sub>3</sub> attenuates inflammation, epidermal structure damage and redness from acute sunburn.<sup>430</sup>

Magnesium is also seen as a common micronutrient deficiency, which is being studied for its relationship to muscle spasm, systemic inflammation, insulin resistance and diabetes, hypertension, and neuropathic pain. There have been positive trials using magnesium infusions for migraine and many emergency rooms employ this intervention.<sup>431,432</sup> Magnesium has also been studied as an NMDA (N-methyl-D-aspartate) receptor blocker in the treatment of neuropathic pain.<sup>433,434</sup> A review of the concomitant use of magnesium with opioids in animals suggests that magnesium may potentiate opioid analgesia while also mitigating some of the adverse effects of opioids including the development of hyperalgesia, improving outcomes in neuropathic pain.<sup>435</sup>

Fish oils high in omega-3 fatty acids, also called polyunsaturated fatty acids (PUFAs), are associated with reduced pro-inflammatory prostaglandins.<sup>436</sup> A 2012 meta-analysis concluded that PUFAs at doses over 2.7 gm/day for over 3 months reduced NSAID consumption in rheumatoid arthritis patients.<sup>437</sup> The north American diet is high in omega-6 fatty acids which are proinflammatory.

Vitamin B12 (cobalamin) deficiency has long been recognized as a cause of neurological disorders including pain. At present, we are only able to measure serum B12 which may or may not reflect B12 levels in the tissues where it is active. There are over 20 recognized genetic abnormalities affecting the cobalamin transport proteins required for intracellular delivery of B12 to tissue targets including mitochondria. Some are severe leading to early failure to thrive

and death and others are states where B12 is insufficient for cellular function despite normal serum levels.<sup>438</sup>

### Other lifestyle factors

Many medications have an adverse effect on micronutrient levels and the health of the microbiome, the mass of microorganisms mainly housed in the gut. Elie Metchnikoff, Nobel Laureate in 1908 for the discovery of cellular immunity, also identified the microbiome as a major determinant of health. Its role in protecting optimal intestinal permeability, modulation of body-wide inflammation, nutrient absorption, and abdominal pain in inflammatory bowel diseases is being widely studied.<sup>197</sup> Poor nutrition and many drugs can adversely affect the microbiome. Proton pump inhibitors deserve special mention in this regard since they are widely used for prolonged periods and their devastating effects on nutritional status has long been unrecognized. The FDA has issued warnings of profound deficiencies in magnesium and calcium, B12 and protein absorption. PPIs also adversely disrupt the microbiome and increase the risk of pathologic dysbiosis and enteric infection such as food poisoning and clostridium difficile.<sup>439</sup> Long term use of PPI medication increases risk of death.<sup>440</sup>

Important behavioral factors such as physical activity level, sleep and stress management can have direct and indirect impact on the experience of pain. Physical activity can be practitioner or instructor directed as in physical therapy, acupuncture therapy, chiropractic, osteopathy, yoga, tai chi, or other movement systems. Additionally, daily physical activity can be and often is self-directed. Physical activity has been shown to increase strength, balance and coordination, reduce pain and improve motor function and mood for patients with hip and knee OA.<sup>441-443</sup> Sleep disorders are commonly seen in pain patients. The disorders may follow or precede the onset of pain.<sup>444</sup> Sleeplessness has been shown experimentally to induce a generalized state of hyperalgesia, a ‘fibromyalgia-like syndrome’.<sup>445</sup> Both pain and pain medications can cause sleep disorders. Sleep apnea is a risk factor for many conditions such as diabetes and hypertension and can be aggravated by medications that are often prescribed for pain patients. Improved sleep leads to improved resilience for pain. Stress has long been reported by patients to be an aggravator of pain.

**In the year 2000, the number of deaths related to poor diet and physical inactivity were 15-16 % of total deaths in the United States, while continuing to increase.’<sup>446</sup>**

## Economic benefits of nonpharmacologic therapies in the treatment of pain

Full economic evaluations, reported as cost-effectiveness analyses (CEA), cost-utility analyses (CUA), and cost-benefit analyses (CBA), often compare costs and health effects between two or more therapies.<sup>447</sup> Low back pain, knee OA and headache are among the most common and costly chronic pain conditions responsible for a significant economic burden on the healthcare system.

There have been extensive economic evaluations of acupuncture therapies for pain conditions. Acupuncture has been shown to be cost-effective in the treatment of chronic, persistent low back pain.<sup>28,207,211,448-450</sup> A cost-effectiveness analysis of nonpharmacologic treatments for knee OA found acupuncture to be one of the more clinically and cost-effective therapies at the UK National Institute for Health and Care Excellence (NICE) QALY (quality adjusted life years) thresholds<sup>294</sup> when done alone or together with exercise-based PT.<sup>451</sup> In a large trial, acupuncture was not only effective in the treatment of neck pain but benefits lasted beyond the three-month study duration, per international cost-effectiveness threshold values, showing acupuncture to be a cost-effective treatment strategy.<sup>292</sup> And while using acupuncture (12 treatments over three months) for migraine and chronic headache increased cost to the UK NHS health service, there was improved health-related quality of life over the year that patients were followed that was favorably cost-effective compared to other NHS provided therapies.<sup>452</sup>

Similarly, the longevity of benefit for acupuncture in chronic pain was evaluated in a meta-analysis of 20 trials and over 6000 patients and showed that clinical benefits of acupuncture were sustained at 12 months after a single course of treatment. Improvements in pain were 90% sustained at 12 months in trials compared to usual care and 50% sustained in trials that compared to sham,<sup>286</sup> with implications for reduction in health care utilization over that period. An update to that meta-analysis of 7 additional years of trials (39 trials, 20,827 patients) confirmed previous findings.<sup>288</sup> The effects of acupuncture were found to persist over time with only a small decrease, approximately 15%, in treatment effect at one year after randomization or 9-10 months after the completion of treatment. A novel finding was additional confirmation of benefit for acupuncture over sham on upper body musculoskeletal pain, neck and shoulder pain.

A curious and compelling finding in a large trial performing a 1 to 1 'propensity score match' (a statistical matching technique that attempts to estimate the effects of a treatment by accounting for the covariates that predict receiving the treatment) of 58,899 patients who received acupuncture for fibromyalgia to 58,899 who did not have acupuncture found the cumulative incidence of coronary heart disease (CHD) was significantly lower in the acupuncture cohort independent of age, sex, comorbidities or statins used.<sup>453</sup>

Systematic reviews have shown manual therapy is a cost-effective treatment for adults with whiplash-associated and neck pain-associated disorders<sup>320</sup> and is also more cost-effective for improving low back and shoulder pain than general practice care that included exercise, stabilization and or advice.<sup>321</sup>

An inclusive review of effective nonpharmacologic therapies for chronic low back pain (33 studies) found cost-effectiveness for combined physical and psychological treatments, medical yoga, information and education programs, acupuncture therapy and spinal manipulation.<sup>211</sup> An earlier review of 26 studies found cost-effectiveness for treatments consistent with the ACP guideline of interdisciplinary rehabilitation, exercise, acupuncture therapy, spinal manipulation and cognitive behavioral therapy for sub-acute and chronic LBP.<sup>454</sup> Group acceptance and commitment therapy (ACT) was found cost-effective for fibromyalgia when compared to medication in a 6 month RCT.<sup>455</sup>

There may be a common perception that nonpharmacologic therapies are an ‘add on’ expense, however, an analysis of the scope of economic benefits changes this perception. There is evidence of cost-effectiveness and costs savings through avoided high tech conventional care, lower future healthcare utilization, and reduction of productive loss for employers.<sup>447</sup> A study by the State of Washington found that even with a substantial number of people using insurance benefits for nonpharmacologic therapies, the effect on insurance expenditures was modest.<sup>118</sup> In a follow-up study of WA state insured patients with back pain, fibromyalgia and menopause symptoms, users of nonpharmacologic therapy providers had lower insurance expenditures than those who did not use them.<sup>119</sup>

Finally, a cost-analysis of an interdisciplinary pediatric pain clinic found interdisciplinary treatment that included acupuncture, biofeedback, psychotherapy and massage with medication management reduced inpatient and emergency department visits and resulted in hospital cost savings of \$36,228/patient/year and in insurance cost savings of \$11,482/patient/year.<sup>456</sup> The findings of the current cost analysis supports that over the course of just one year, participation in an outpatient individually-tailored interdisciplinary pain clinic can significantly reduce costs by more than the cost of the intervention itself.

### *Course of treatment and cost for inpatient acute care*

Inpatient acute pain care can follow a course of as little as one treatment to several treatments, as in daily treatment over the course of a hospital stay. Inpatient acupuncture sessions can be given at a patient’s bedside and sessions can last from 20-45 minutes or longer and is recommended in the 24 hours or less before surgery, after surgery, and daily as requested by inpatients or their caregivers. An integrative medicine approach using yoga therapy, holistic nursing techniques and a ‘healing environment’ used in inpatient oncology had an immediate term cost benefit from reduced use of antiemetic, anxiolytic and hypnotic medication costs in the amount of \$156/day/patient. If extrapolated to the number of patients, beds and days of operation for the unit studied this would result in a savings of nearly one million dollars a year.<sup>457</sup>

### *Course of treatment and costs for outpatient chronic pain*

Projections of costs for a course of treatment of an evidence-based nonpharmacologic therapy will vary depending on the geographic area, health system, and access to care options. First, a course of care recommendation would be based on studies as well as systematic reviews and meta-analyses of effectiveness trials. A recommended course of treatment for chronic pain will depend on the patient and the term and severity of the condition.

In a large meta-analysis of RCTs of acupuncture for chronic pain of the head, neck, shoulder, low back, and knee where benefit persisted significantly (12 months) following a course of treatment, patients received on average 8-15 treatments over 10-12 weeks.<sup>208</sup> In the Cochrane Reviews recommending acupuncture for tension headache<sup>297</sup> and migraine,<sup>298</sup> a minimum of 6 sessions was required for inclusions in the review. Weekly treatment was common; no trials gave acupuncture more than twice per week.<sup>376</sup> Based on these studies, referral for acupuncture therapy is recommended for at least 8 sessions, and preferably 8-15 weekly sessions of care. For a severe or acute ambulatory pain event, initial treatment frequency may be more than once per week. Acupuncture therapy cost per session varies from \$60-120<sup>458</sup> or more, with the initial session longer and higher in cost. A course of ambulatory care of 10 sessions then can range from \$700.00 to \$1300 or more.

Acupuncture therapy delivered in a group setting is being studied as an option for underserved populations,<sup>377</sup> in line with research on group medical visits,<sup>378</sup> and group-style self-management interventions.<sup>459</sup> Costs are reduced, with care overlapping in a shared treatment space. Group sessions can be less than half the cost of an individual session.

Chiropractic and osteopathic manipulation sessions are structured as individual care with additional costs of techniques like ultrasound that may be applied by an assistant. Session can be more than once a week to once a week for maintenance. Costs of sessions vary from \$35 to \$106<sup>460</sup> or more for 30 minutes with averages \$65-\$70 depending on the region of the country. Charges may increase with a-la-carte fees for interventions in addition to manipulations, such as applications of heat or cold, for example.

Massage therapy is generally offered in weekly sessions with costs varying from \$60-\$90 or more for a 60-minute session, less for shorter sessions, more for longer sessions. Fees also depend on the site, whether a clinic, gym, spa, hotel or practitioner's office.

Movement therapies like Tai chi and yoga are typically given in group sessions, and have been studied in a term of intervention from 1-5 sessions per week for 6 weeks to a year for Tai chi<sup>362,366</sup> and as 12 weekly sessions of 75 minutes for yoga.<sup>358</sup> Session fees can range from \$10-20, with prices reduced with purchases of multiple sessions or more if private or semi-private sessions. Similarly, sessions for Pilates, Feldenkrais or Alexander technique are paid as individual sessions or reduced if bought as a package for multiple sessions. Pilates costs anywhere from \$15-\$55 for 45-minute group mat classes, \$35-\$85 for group classes using equipment, and private sessions costing upwards of \$50-\$150 per one-hour session.<sup>461</sup> Feldenkrais is offered as private, semi-private or group sessions with costs varying from \$50 to \$90 for private and \$10 to \$25 for classes.<sup>462</sup> Alexander technique sessions vary in cost

depending on country or region but are generally on par with massage therapy costs if given in private sessions, less if given in a group setting.

MBSR has been shown to be cost-effective and cost-saving for patients with low back pain.<sup>212</sup> An 8-week course of MBSR ranges from \$500 to \$600 or more depending on the area of the country.

In general, the costs of evidence-based nonpharmacologic options are nominal compared to medical costs of treating chronic pain with risk mitigation and greater potential for engaging patients in ongoing self-care.

## Recommendations

### Education, treatment and research

Many in medicine and policy decision-making acknowledge the crisis in pain and pain care detailed in this paper and seek evidence-based solutions for successful comprehensive pain management. Currently most of the nonpharmacologic strategies reviewed here are underutilized due to lack of evidence dissemination, education and reimbursement. It is time for civilian medicine to join the call to action of military medicine outlined by Schoomaker and Buckenmaier in ‘If not now, when? If not you, who?’ urging the immediate incorporation of effective nonpharmacologic modalities and active self-care because of their safety, effectiveness and acceptance by patients.<sup>463</sup> The goal in these recommendations and the call to action that follows is to increase awareness, access and utilization of safe, effective nonpharmacologic treatments through education of practitioners and patients; dissemination of and reimbursement for evidence-based treatment options; and to promote ongoing research focused on the therapeutic and economic impact, in the short and long term, of comprehensive care practices.

### Education

The training of physicians and health care providers must include current pain mechanisms and all evidence-based treatment options for pain including effective nonpharmacologic options as stand-alone first line of care and as part of individualized comprehensive pain care.

This includes individualized pain care that is patient-centered and evidence-informed

1. Patient-centered care focuses on each person’s unique healthcare needs and experiences by asking
  - a. How do you manage pain now and in the past?
  - b. What nonpharmacologic strategies have you used?
  - c. What are you interested in exploring?
2. Practitioners should become familiar with nonpharmacologic modalities and licensed independent practitioners in their system and or area of practice.

### ***Treatment: nonpharmacologic therapy frequency, dosage and timing***

While physicians are familiar with dosage of medications, evidence-informed frequency, ‘dosage’ and timing of nonpharmacologic therapies is less well disseminated. Inpatient care is recommended to be daily care or every other day when staggered with another available nonpharmacologic intervention. In acute extreme pain that is not well managed, a second same or different treatment may be needed in a single day.

#### ***Evidence-based nonpharmacologic options for inpatient acute pain care include:***

1. Acupuncture therapy, massage therapy, mind/body interventions such as music therapy, transcutaneous electric nerve stimulation (TENS).
2. Daily inpatient access to effective nonpharmacologic care is recommended.

Recommendations and referral must take into account a patient’s unique presentation and circumstances in terms of access and coverage. Even when not covered by insurance, a course of nonpharmacologic treatment may have a longitude of benefit that exceeds short term benefit of medications that are accompanied by adverse events and addiction liability.

#### ***Evidence-informed nonpharmacologic options for chronic pain include:***

1. Acupuncture therapy, chiropractic and osteopathic care, massage therapy, physical therapy, mind/body and movement therapies, cognitive behavioral therapy
2. Referral to a course of effective nonpharmacologic care is recommended.

### ***Research***

The call for research includes studies on the timing, dosage, frequency, longitude and combinations of care in the development of a comprehensive pain care model for both the inpatient and outpatient setting.

Stakeholders must petition and support evidence-informed policy guidelines to increase access to and coverage for effective nonpharmacologic options as an essential part of comprehensive pain care.

## SECTION 3- CALL TO ACTION

As detailed in this paper, documented in the literature and accepted by health professionals and researchers, the crisis in pain care and aspects of current pain management strategies are having enormous detrimental impacts on patients, the health system and society.<sup>1,2</sup> In response to the grim statistics about pain care and the opioid epidemic, health care professionals, policy makers, researchers and multiple major health organizations and government agencies are moving in the right direction. The IOM,<sup>1</sup> NAM,<sup>2</sup> NIH,<sup>4</sup> the CDC,<sup>193</sup> The Joint Commission,<sup>194</sup> the military,<sup>463</sup> the FDA,<sup>195</sup> the ACP<sup>196</sup> and the former US Surgeon General<sup>464</sup> concede that past strategies and the use of opioid medications have not remedied but rather exacerbated chronic pain, abuse, addiction, illness behavior and disability and call for evidence-based, comprehensive pain care, to include nonpharmacologic therapies.

While there is consensus that pain care must drastically improve and prioritize evidence-based nonpharmacologic treatments, there is a need for an informed strategy that includes all evidence-based and comprehensive pain care. Currently, most of the nonpharmacologic strategies outlined in the preceding review are underutilized due to inadequate dissemination of evidence, professional and public education and inadequate reimbursement.

### **The Consortium Pain Task Force goals in a call to action are to:**

- increase awareness of effective nonpharmacologic treatments for pain
- train healthcare practitioners and administrators in the evidence base of effective nonpharmacologic practice
- advocate for policy initiatives that remedy system and reimbursement barriers to evidence-informed comprehensive pain care and
- promote ongoing research and dissemination of the role of effective nonpharmacologic treatments in pain, focused on the short and long term therapeutic and economic impact of comprehensive care practices

This paper is a bold call to action for policy makers, hospitals and health systems, insurers, primary care providers and other licensed health practitioners and health care educators to lead in effecting this change.

## **POLICY: Federal and state policy should increase access to and reimbursement for evidence-based nonpharmacologic therapies**

Based on the literature, stakeholders must petition and support evidence-based policy guidelines to increase access to and coverage for nonpharmacologic options as an essential part of comprehensive pain care.

**Federal policy:** Currently, there is evidence of effectiveness, cost-effectiveness, cost-savings and risk mitigation for evidence-based nonpharmacologic options. Nonpharmacologic therapies for pain are now recommended by the NIH, FDA, TJC, CDC and ACP. Federal reimbursement policy needs to be based on current evidence of effectiveness, cost-effectiveness and risk mitigation and include nonpharmacologic care.

**State policy:** States need to adopt policies of coverage and plans for access to pain care based on current evidence of effectiveness, cost-effectiveness, cost-savings and risk mitigation that includes effective nonpharmacologic therapies. Policy should require private insurers to cover evidence-informed nonpharmacologic therapies for acute and chronic pain.

## **BEST PRACTICES: Identify and develop clinical models that integrate evidence-based nonpharmacologic therapies for pain**

Develop, optimize, incentivize and coordinate care across disciplines with non-discriminatory access to evidence-based nonpharmacologic therapies, as stand-alone first line of care and as essential part of comprehensive care.

## **EDUCATION: Deliver evidence-based training to learners and graduates of the health care system in all disciplines on pain and effective nonpharmacologic treatments for pain**

As recommended by the National Academy of Medicine (NAM), pain-related education for all health professionals who provide care to people with pain must become a national mandate.<sup>82</sup> Academic health care education should train students and health practitioners on the evolving understanding of pain and its complexities, including physical and psychiatric comorbidities and substance abuse disorder (SUD) as well as evidence-based frequency, ‘dosage’ and timing of effective nonpharmacologic therapies. Health care practitioners require education and practical changes in practice models to enable them to be responsible to inform and educate patients on evidence-based comprehensive models of pain care including self-efficacy, patient responsibility, self-care and lifestyle choices.

## **RESEARCH: Identify and fund research to evaluate health outcomes and economic impact of comprehensive pain care that includes effective nonpharmacologic therapies**

The call for research includes studies on the timing, dosage, frequency, longitude of benefit and combinations of care in the development of a comprehensive pain care model for both the inpatient and outpatient setting. NIH, NCCIH, AHRQ, CMS and other agencies and foundations should seek to fund investigation of comprehensive models of pain care and their impact on health outcomes, potential opioid sparing and reduction of opioid liability overuse and dependency.

## **DISSEMINATION: Stakeholder groups need to engage the media and foster public awareness of comprehensive pain care options that include evidence-based nonpharmacologic therapies**

Academic organizations, pain societies, medical societies, patient advocacy groups, insurance carriers, and the media have important roles in the dissemination and education of their members and the public regarding the benefits of nonpharmacologic options of pain care. Dissemination facilitates general and individual patient-practitioner conversations on options for personal comprehensive pain care.

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## List of organizations and abbreviations

<p><b>ACP</b> American College of Physicians  <b>ACT</b> Acceptance and Commitment Therapy  <b>AHRQ</b> Agency for Healthcare Research and Quality,  U.S. Department of Health and Human Services  <b>APAP</b> acetaminophen  <b>APRN</b> nurse practitioners  <b>AT</b> Alexander Technique  <b>CBA</b> cost-benefit analyses  <b>CBD</b> cannabidiol  <b>CBT</b> Cognitive behavioral therapy  <b>CDC</b> Centers for Disease Control  <b>CEA</b> cost-effectiveness analyses  <b>CFO</b> Chief Financial Officer  <b>CHD</b> coronary heart disease  <b>cLBP</b> chronic low back pain  <b>CMS</b> Centers for Medicare and Medicaid Services  <b>CNCP</b> chronic noncancer pain  <b>CUA</b> cost-utility analyses  <b>ED</b> Emergency Department  <b>eHealth</b> web-based health interventions  <b>E-stim</b> electrical stimulation  <b>FDA</b> Food and Drug Administration,  U.S. Department of Health and Human Services  <b>HVLA</b> high velocity, low amplitude thrust techniques  (SMT, MT)  <b>IBI</b> Integrated Benefits Institute  <b>IOM</b> Institute of Medicine, now NAM  <b>IV</b> intravenous  <b>LVLA</b> low velocity, low amplitude thrust technique  (SMT, MT)  <b>MBSR</b> Mindfulness-Based Stress Reduction  <b>MT</b> manipulative therapy, manual therapy  including massage therapy</p>	<p><b>NAM</b> National Academy of Medicine  <b>NAS</b> neonate abstinence syndrome  <b>NCCIH</b> National Center for Complementary and  Integrative Health, NIH  <b>NHIS</b> National Health Interview Survey  <b>NICE</b> UK National Institute for Health and Care  Excellence  <b>NIDA</b> National Institute for Drug Abuse  <b>NIH</b> National Institutes of Health,  US Department of Health and Human Services  <b>NMDA</b> N-methyl-D-aspartate  <b>NSAID</b> nonsteroidal anti-inflammatory drug  <b>OHP</b> Oregon Health Plan, Oregon’s Medicaid Program  <b>OA</b> Osteoarthritis  <b>PA</b> Physician’s Assistant  <b>PCP</b> Primary Care Practitioner, Physician  <b>PCST</b> pain-coping skills training  <b>PM&amp;R</b> physical medicine and rehabilitation  <b>PMTF</b> The Office of the Army Surgeon General  Pain Management Task Force  <b>PT</b> physical therapy  <b>PTSD</b> post-traumatic stress disorder  <b>PUFA</b> polyunsaturated fatty acids  <b>QALY</b> quality adjusted year of life  <b>QOL</b> quality of life  <b>ROI</b> return on investment  <b>S&amp;P</b> Standard and Poor’s 500 Index  <b>SMT</b> spinal manipulation therapy  <b>SUD</b> substance use disorder  <b>TENS</b> transcutaneous electric nerve stimulation  <b>THC</b> tetrahydrocannabinol  <b>TJC</b> The Joint Commission</p>
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#### **I.4 National Academies Consensus Report on Opioid Epidemic and Pain 2017**

This document is too large to attach so we are including reference to it.

National Academies of Sciences, Engineering, and Medicine. 2017. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24781>.

## Critical Reviews

# Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis



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**Abstract:** Despite wide use in clinical practice, acupuncture remains a controversial treatment for chronic pain. Our objective was to update an individual patient data meta-analysis to determine the effect size of acupuncture for 4 chronic pain conditions. We searched MEDLINE and the Cochrane Central Registry of Controlled Trials randomized trials published up until December 31, 2015. We included randomized trials of acupuncture needling versus either sham acupuncture or no acupuncture control for nonspecific musculoskeletal pain, osteoarthritis, chronic headache, or shoulder pain. Trials were only included if allocation concealment was unambiguously determined to be adequate. Raw data were obtained from study authors and entered into an individual patient data meta-analysis. The main outcome measures were pain and function. An additional 13 trials were identified, with data received for a total of 20,827 patients from 39 trials. Acupuncture was superior to sham as well as no acupuncture control for each pain condition (all  $P < .001$ ) with differences between groups close to .5 SDs compared with no acupuncture control and close to .2 SDs compared with sham. We also found clear evidence that the effects of acupuncture persist over time with only a small decrease, approximately 15%, in treatment effect at 1 year. In secondary analyses, we found no obvious association between trial outcome and characteristics of acupuncture treatment, but effect sizes of acupuncture were associated with the type of control group, with smaller effects sizes for sham controlled trials that used a penetrating needle for sham, and for trials that had high intensity of intervention in the control arm. We conclude that acupuncture is effective for the treatment of chronic pain, with treatment effects persisting over time. Although factors in addition to the specific effects of needling at correct acupuncture point locations are important contributors to the treatment effect, decreases

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in pain after acupuncture cannot be explained solely in terms of placebo effects. Variations in the effect size of acupuncture in different trials are driven predominantly by differences in treatments received by the control group rather than by differences in the characteristics of acupuncture treatment.

**Perspective:** *Acupuncture is effective for the treatment of chronic musculoskeletal, headache, and osteoarthritis pain. Treatment effects of acupuncture persist over time and cannot be explained solely in terms of placebo effects. Referral for a course of acupuncture treatment is a reasonable option for a patient with chronic pain.*

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**Key words:** *Acupuncture, chronic pain, meta-analysis, osteoarthritis, back pain, neck pain, migraine.*

Acupuncture remains a controversial treatment for chronic pain, largely because of a provenance outside biomedicine. Traditional acupuncture theory invokes nonanatomical structures such as meridians and nonphysiological processes such as the flow of qi energy. Although many contemporary practitioners do not rely on such concepts, there remains a dearth of data on how insertion of needles at specific points on the body could lead to long-term decreases in pain. Acupuncture undoubtedly has short-term physiological effects, several of which are relevant to pain,<sup>7,76,119</sup> but there is as yet no explanation as to how such effects could persist.

We previously reported an individual patient data meta-analysis of high-quality trials of acupuncture for chronic pain.<sup>93</sup> Differences between acupuncture and control in trials without sham (placebo) control were statistically as well as clinically significant. Acupuncture was significantly superior to sham control, suggesting that acupuncture effects are not solely explicable in terms of placebo, although these differences were relatively modest. We have separately reported secondary analyses examining whether characteristics of acupuncture treatment<sup>66</sup> or control groups<sup>68</sup> influence effect size, and whether the effects of acupuncture treatment persist over time.<sup>69</sup> In this article we update our previous analyses now including studies published during the past 7 years.

## Methods

The full protocol of the meta-analysis<sup>92</sup> and the results of the first individual patient data meta-analysis including randomized controlled trials (RCTs) published up to November 2008<sup>93</sup> have been published. The literature search was repeated to identify eligible RCTs published between December 2008 and December 2015. Trials were considered eligible if they accrued patients with non-specific back or neck pain, shoulder pain, chronic headache, or osteoarthritis; pain duration was at least 4 weeks for musculoskeletal disorders; at least 1 group received acupuncture needling and 1 group received either sham acupuncture or no acupuncture control; the primary end point was measured more than 4 weeks after the initial acupuncture treatment; and allocation concealment was determined unambiguously to be adequate. Principal investigators of eligible studies were asked to provide raw data. These raw data were used to replicate all analyses published in the original RCT publication to ensure data accuracy. Each trial was reanalyzed using analysis of covariance with the standardized primary end

point (scores divided by pooled SD) as the dependent variable, and the baseline measure of the primary end point and variables used to stratify randomization as covariates. The primary outcome for each study was that identified by the responding author of each study. The effect sizes for each study were then entered into a meta-analysis using the `metan` command in Stata (version 13, StataCorp, College Station, TX). Fixed effects as well as random effects estimates were calculated. Fixed effects weights were calculated using inverse-variance weighting, and random effects weights were calculated using the DerSimonian and Laird method. We prespecified that meta-analyses would be conducted separately for comparisons of acupuncture versus sham and acupuncture versus no acupuncture control, and within each pain type, and the hypothesis test would be on the basis of the fixed effects analysis. In the original article, trials for which individual patient data were not available were included as a sensitivity analysis; in this update, we include summary data for such trials in the main meta-analysis and exclude them as a sensitivity analysis.

As secondary analyses, we examined whether characteristics of acupuncture treatment modified treatment effects. Trial-level as well as patient-level analyses were performed. For trial-level analyses, we used random effects meta-regression to test the effect of each characteristic on the main effect estimate using the Stata command `metareg`. For patient-level analyses, we created a linear regression as for the main analysis of effect size, but included the characteristic and an interaction term between the characteristic and treatment allocation. The coefficient was then entered into a meta-analysis. In both analyses, random effects estimates and 95% confidence intervals were reported; *P* values were on the basis of the fixed effects analysis. We also analyzed the effect of acupuncture relative to different types of sham acupuncture and different types of no acupuncture control group. Three comparisons of sham acupuncture were investigated: penetrating needle versus nonpenetrating needle as well as non-needle sham; nonpenetrating needle versus non-needle sham; and the use of true acupuncture points versus nonacupuncture points among trials using nonpenetrating or non-needle sham. For sham arms using penetrating needles, there was also a comparison done between the use of deep needle penetration and shallow needle penetration. We entered the effect size and standard error for each trial into a meta-regression along with the type of sham acupuncture used in that trial. For this analysis, smaller effect sizes indi-

cate a smaller difference in effect between verum acupuncture and sham acupuncture, implying that the type of sham acupuncture used is more active and therefore more similar to verum acupuncture. For the analysis of acupuncture effect relative to the no acupuncture control group, we used meta-regression to compare the effects of trials using no acupuncture control groups characterized as high intensity, usual care, or low intensity. We also repeated our previous analyses exploring possible effects of publication bias and exploring differences between sham acupuncture and no treatment.

## Results

### Systematic Review

Our systematic review<sup>93</sup> was updated to include trials published after November 2008 and before December 31, 2015. We identified 75 additional RCTs, of which 13 were eligible (Fig 1). These 13 studies include 4 trials<sup>19,56,75,85</sup> included as summary data only in a sensitivity analysis in our first report.

### Data Extraction and Quality Assessment

Individual patient data for 2,905 patients were received from 10 of these 13 studies and included patients from the United States, Australia, China, Germany, and the United Kingdom. For 1 of the 3 studies for which we

did not receive data, the statisticians involved in the RCT failed to respond to repeated inquiries despite approval for data sharing being obtained from the principal investigator. For the other 2 studies, the trial authors were contacted and invited to participate but we received no further response. These 3 studies were included in the analysis as summary data only using the published estimates of effect size.<sup>31,70,75</sup> Two trials from the original systematic review for which data were not received were also included as summary data in these analyses.<sup>23,74</sup>

A total of 20,827 patients were included in the total 39 trials (Table 1). The trials comprised 25 comparisons with 16,041 patients of acupuncture and no acupuncture control, and 26 comparisons with 7,237 patients of acupuncture and sham acupuncture control. Of the trials on musculoskeletal pain, most had an eligibility criterion of a minimum 3 or 6 months' pain duration. Among those for which individual patient data on chronicity were available, the median duration was 4 years (quartiles: 1.1 years, 10 years). There were 2 trials for which the time period between first symptom and evaluation of outcome could theoretically have been <3 months on the basis of eligibility criteria and timing of assessment. For Irnich et al, the duration of disease was "4 to 52 weeks" for 19% of patients and >1 year for the remainder.<sup>41</sup> In the case of Kleinhenz et al, no data were provided on chronicity, however, the indication was rotator cuff tendinitis, which is rarely treated in the acute phase.<sup>52</sup> We conclude that all but a trivial proportion of patients included in the

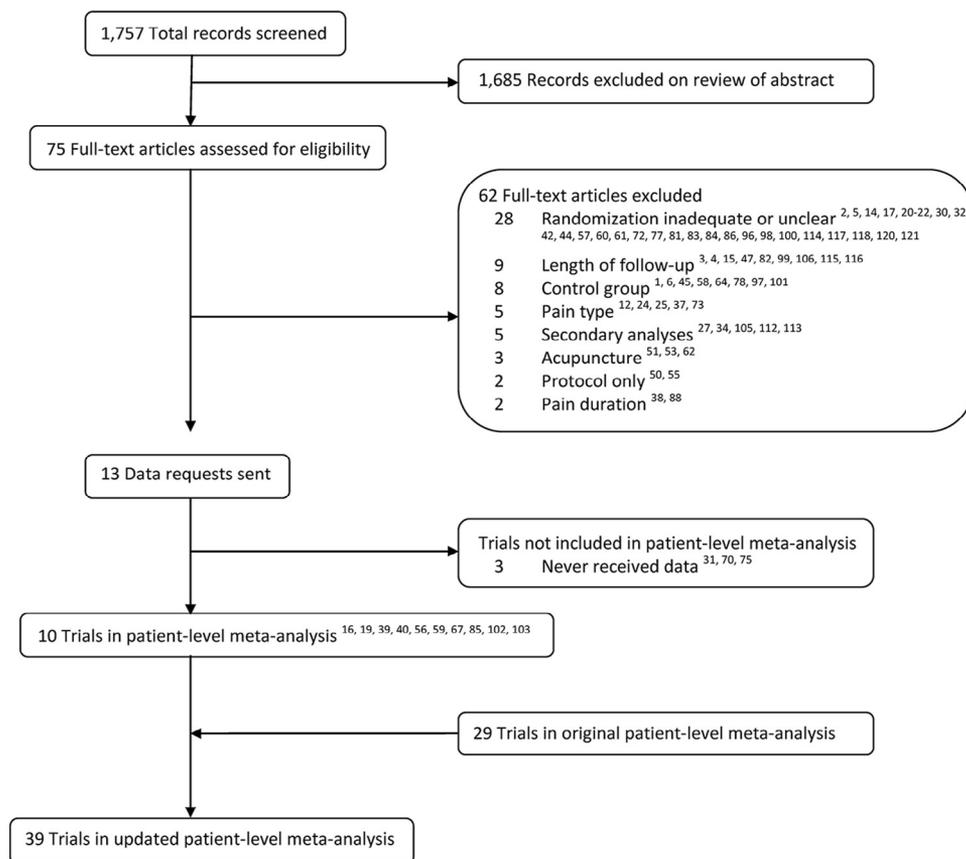


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. Appendices - Page A- 205

**Table 1. Characteristics of Included Studies**

INDICATION (N = 44)	PAIN TYPE	CONTROL GROUP	PRIMARY OUTCOME MEASURE	TIME POINT
Chronic headache (n = 9)	Migraine (n = 3), <sup>26,59,63</sup> tension-type headache (n = 3), <sup>23,28,71</sup> both <sup>31,43,95</sup> (n = 3)	Sham control (n = 5) <sup>26,28,59,63,71</sup> ; no acupuncture control (n = 7); ancillary care (n = 2) <sup>23,31</sup> ; usual care (n = 4) <sup>43,63,71,95</sup> ; guideline care (n = 1) <sup>26</sup>	Severity score (n = 2) <sup>23,95</sup> ; days with headache (n = 3) <sup>28,43,71</sup> ; days with migraine (n = 2) <sup>26,59</sup> ; days with moderate to severe pain (n = 1) <sup>63</sup> ; Migraine Disability Assessment (n = 1) <sup>31</sup>	1 Month (n = 1) <sup>23</sup> 2 Month (n = 1) <sup>31</sup> 3 Month (n = 3) <sup>43,63,71</sup> 4 Month (n = 1) <sup>59</sup> 6 Month (n = 2) <sup>26,28</sup> 12 Month (n = 1) <sup>95</sup>
Nonspecific musculoskeletal pain (back and neck; n = 18)	Back (n = 12) <sup>11,13,18,19,36,40,48,49,74,87,102,111</sup> ; neck (n = 6) <sup>41,67,79,91,104,109</sup>	Sham control (n = 10) <sup>11,13,19,36,41,48,49,74,91,104</sup> ; no acupuncture control (n = 12); ancillary care (n = 3) <sup>40,74,102</sup> ; usual care (n = 7) <sup>11,19,67,79,87,109,111</sup> ; nonspecific advice (n = 1) <sup>18</sup> ; guideline care (n = 1) <sup>36</sup>	VAS (n = 7) <sup>11,13,41,49,74,91,104</sup> ; Roland Morris Disability Questionnaire (n = 3) <sup>18,19,48</sup> ; Northwick Park Neck Pain Questionnaire (n = 2) <sup>67,79</sup> ; SF-36 bodily pain (n = 2) <sup>87,102</sup> ; Hannover Functional Questionnaire (n = 1) <sup>111</sup> ; Von Korff pain score (n = 1) <sup>36</sup> ; Oswestry Disability Index (n = 1) <sup>40</sup>	1 Month (n = 4) <sup>41,49,91,104</sup> 2 Month (n = 3) <sup>11,18,19</sup> 3 Month (n = 5) <sup>48,74,79,109,111</sup> 4 Month (n = 1) <sup>102</sup> 6 Month (n = 2) <sup>36,40</sup> 8 Month (n = 1) <sup>13</sup> 12 Month (n = 1) <sup>67</sup> 24 Month (n = 1) <sup>87</sup>
Osteoarthritis (n = 13)		Sham control (n = 10) <sup>8,16,33,39,70,80,85,89,103,108</sup> ; no acupuncture control (n = 10); ancillary care (n = 3) <sup>33,70,80</sup> ; usual care (n = 5) <sup>39,56,85,108,110</sup> ; nonspecific advice (n = 2) <sup>8,107</sup>	WOMAC (n = 5) <sup>16,56,70,108,110</sup> ; WOMAC pain subscore (n = 4) <sup>8,33,80,89</sup> ; Oxford Knee score questionnaire (n = 1) <sup>107</sup> ; VAS <sup>103</sup> (n = 1); knee pain (0–10) (n = 1) <sup>39</sup> ; joint-specific Multidimensional Assessment of Pain (n = 1) <sup>85</sup>	1 Month (n = 1) <sup>103</sup> 2 Month (n = 3) <sup>70,107,108</sup> 3 Month (n = 6) <sup>16,39,56,85,89,110</sup> 6 Month (n = 3) <sup>8,33,80</sup>
Shoulder pain (n = 4)		Sham control (n = 4) <sup>35,52,75,90</sup> ; No-acupuncture control (n = 1); ancillary care (n = 1) <sup>75</sup>	Constant-Murley score (n = 2) <sup>52,90</sup> ; VAS (n = 2) <sup>35,75</sup>	1 Month (n = 2) <sup>52,90</sup> 6 Month (n = 2) <sup>35,75</sup>

Abbreviations: VAS, visual analog scale; SF-36, 36-Item Short Form Health Survey; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

analysis would have met the conventional definition of chronic pain, that is, pain lasting at least 3 to 6 months. Six sham RCTs were determined to have an intermediate likelihood of bias from unblinding.<sup>13,26,41,49,59,103</sup> In 1 trial, 2 types of sham acupuncture were used, although only 1 type (non-needle sham acupuncture) was found to have an intermediate likelihood of bias from unblinding.<sup>103</sup> One trial (Hinman et al) was determined to have a sham acupuncture arm with a high likelihood of bias from unblinding.<sup>39</sup> This trial was excluded from the main analyses comparing acupuncture with sham acupuncture, but a sensitivity analysis including this trial was performed. None of the 10 new trials included in this analysis had dropout rates of >25%.

### Meta-Analysis

Forest plots for acupuncture against sham acupuncture and against no acupuncture control are shown separately for each of the 4 pain conditions in Fig 2 and Fig 3. Fixed effects weights are reported in Figs 2 and 3; forest plots with random effects weights reported are presented in Supplementary Figs 1 and 2. Meta-analytic statistics are shown in Table 2. Consistent with the results of the originally published meta-analysis, acupuncture is found to be statistically superior to control for all analyses ( $P < .001$ ). Effect sizes in the updated analyses are similar to those in the original analyses, with effect sizes changing by  $\leq .02$  for most comparisons. Effect sizes are close to .5 compared with no acupuncture control and .2 compared with sham. To illustrate these effect sizes in more clinically applicable terms, if baseline pain score in a typical RCT was 60 on a scale of 0 to 100, with an SD of 25, follow-up scores might be 43 in a no acupuncture control group, 35 in a sham acupuncture group, and 30 among true acupuncture patients. If response was defined as a pain reduction of 50% or more, response rates would be approximately 30%, 42.5%, and 50%, respectively. Also in keeping with the original analyses, significant heterogeneity was found in 5 of 7 comparisons. Significant heterogeneity remained for sham-controlled musculoskeletal pain and osteoarthritis ( $P = .001$  and  $P < .001$ , respectively) even after excluding the outlying Vas et al trials.<sup>89-91</sup> There was also significant heterogeneity for all indications in the comparison of acupuncture with no acupuncture control. Heterogeneity is further explored (see the section on "Modifiers of Trial Outcome").

### Sensitivity Analyses

Prespecified sensitivity analyses are also shown in Table 2. The exclusion of the RCTs by Vas et al<sup>89-91</sup> repeats our previous finding that the effect sizes for comparison with sham are similar for musculoskeletal pain, osteoarthritis, and chronic headache. However, there are now sufficient trials for a meta-analysis of shoulder pain trials without inclusion of Vas et al<sup>90</sup> and the effect size for this indication is clearly much greater. There is also a large effect size for sham controlled neck pain trials when these are analyzed separately from back pain. Most other sensitivity analyses had little effect on the main find-

ings. Analyses incorporating assessment of patient blinding, missing data, or trials without individual patient data, all had results very similar to the primary analysis. Because the primary outcome included in the analysis was the outcome specified by the trial authors, we also performed a sensitivity analysis restricted to a single end point (pain intensity) at a fixed follow-up time (2–3 months after randomization). Results were again very similar apart from sham-controlled trials of musculoskeletal pain (Table 3), in which effect size decreased from .30 to .13, but this appears to be attributable to there being only 5 of 11 trials that measured pain intensity at 2 to 3 months, and the trials excluded happened to be those with the larger effect sizes.

We combined all trials into 1 meta-analysis for all indications to assess the possible effect of publication bias. As in the original analyses, we found some evidence that smaller studies had larger effect sizes for the sham comparison ( $P = .024$ ), but not for the no acupuncture comparisons ( $P = .75$ ). No significant asymmetry was seen after excluding the Vas trials<sup>89-91</sup> and shoulder pain trials<sup>35,52,75,90</sup> from the sham comparison ( $n = 21$ ,  $P = .13$ ), and also when excluding any trials with fewer than 100 patients ( $n = 21$ ,  $P = .069$ ). We found that the difference between acupuncture and control would become non-significant only if there were 51 and >100 unpublished trials with 100 patients and effect sizes in favor of control of .25 SD for sham and no acupuncture control, respectively.

We also repeated our exploratory analysis comparing sham control with no acupuncture control. In a meta-analysis of 12 RCTs that had sham as well as no acupuncture control arms, the effect sizes for sham were .39 (95% confidence interval [CI] = .33–.45) and .45 (95% CI = .29–.61) for fixed and random effects, respectively ( $P < .0001$  for tests of effect as well as heterogeneity).

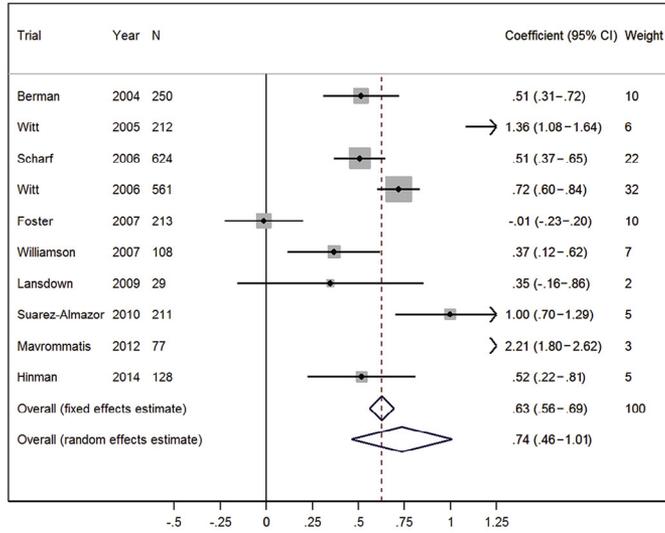
### Modifiers of Trial Outcome

In addition to updating the primary analyses, we also updated previously published analyses on how characteristics of the acupuncture and control interventions influence trial outcomes. Trial-level and patient-level characteristics are shown in Tables 4 and 5, respectively.

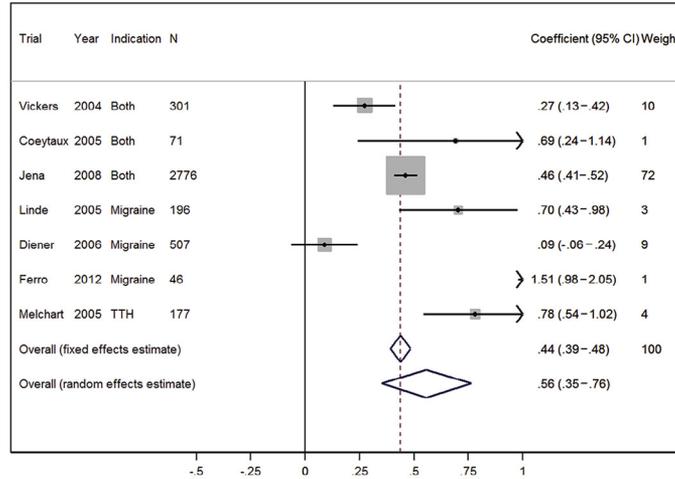
### Acupuncture Characteristics Analysis

We updated previously reported analyses examining whether characteristics of acupuncture treatment modified the effect of acupuncture relative to control. These analyses include trial-level analysis, on the basis of characteristics described in the study protocol, as well as patient-level analyses, on the basis of data related to the individual patient. The results are shown in Table 6. We did not find any obvious association between trial outcome and characteristics such as the style of acupuncture (traditional or Western), use of fixed versus individualized point selection, or the use of electrical stimulation. The only clear finding was a dose-response effect to number of acupuncture treatments in trials with a no acupuncture control group (increase in effect size of .10 per 5 sessions, 95% CI =  $-.01$  to  $.21$ ,  $P = .001$ ).

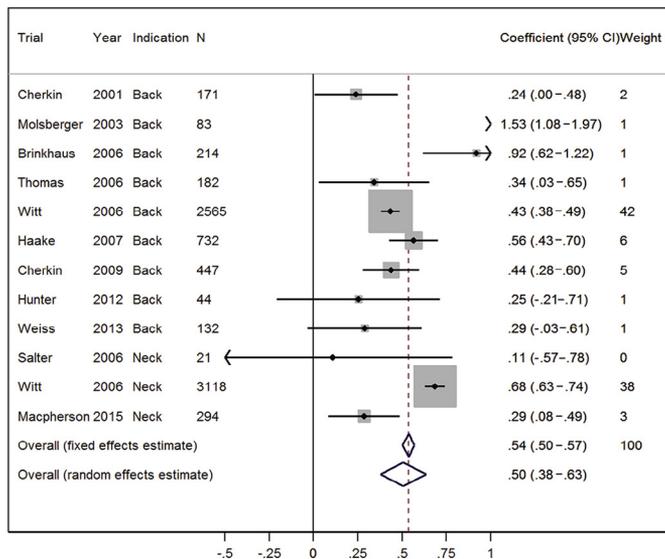
### Osteoarthritis



### Headache

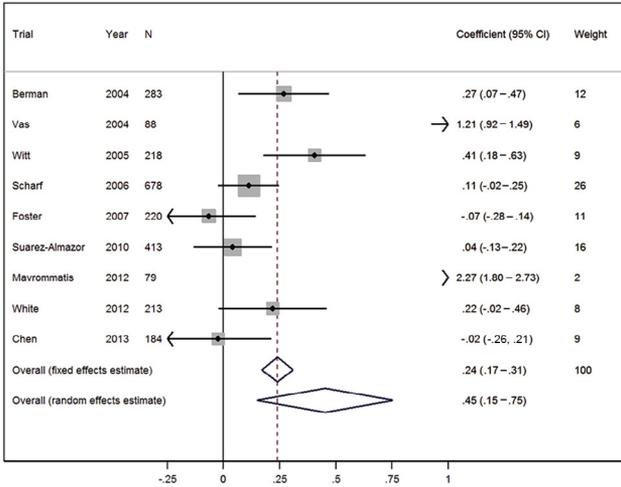


### Musculoskeletal Pain

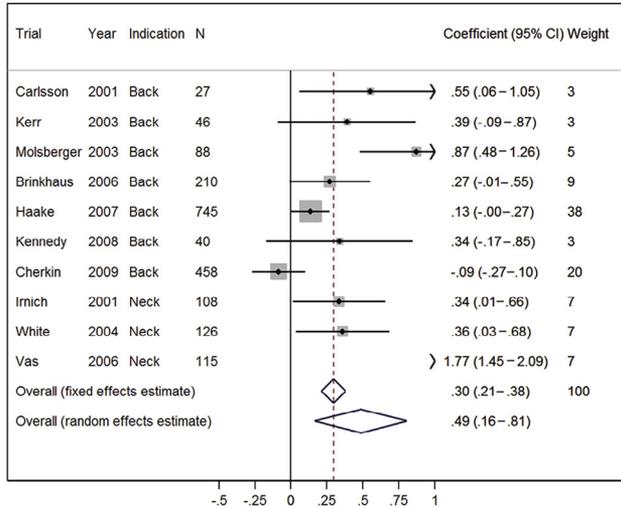


**Figure 2.** Forest plots for the comparison of acupuncture with no acupuncture control. There were fewer than 3 trials for shoulder pain, so no meta-analyses were performed. Weights reported are fixed effects weights calculated using inverse variance weighting.

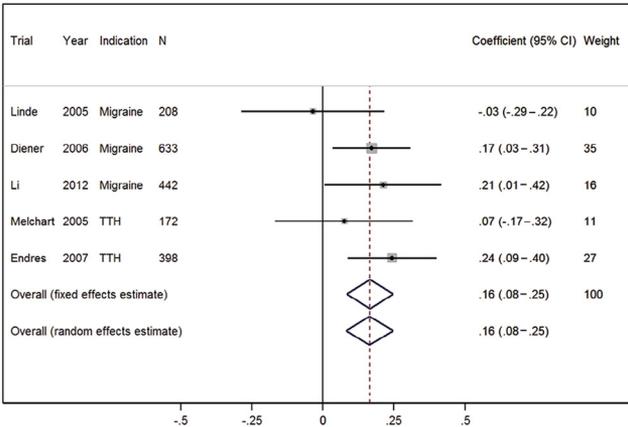
**Osteoarthritis**



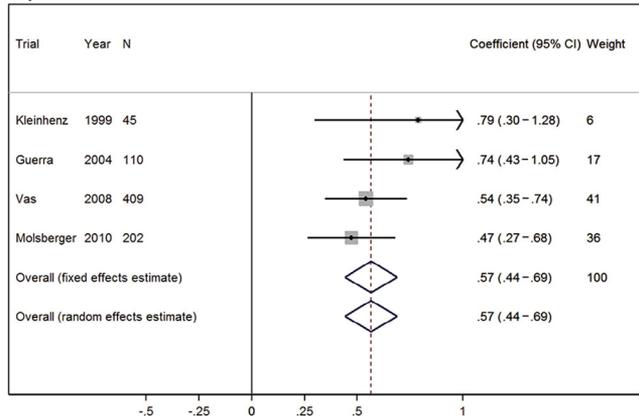
**Musculoskeletal Pain**



**Headache**



**Specific Shoulder Pain**



**Figure 3.** Forest plots for the comparison of true and sham acupuncture. Weights reported are fixed effects weights calculated using inverse variance weighting.

**Sham Acupuncture Control Analysis**

We also updated a previously published analysis investigating the effects of acupuncture relative to different types of sham acupuncture and no acupuncture control groups. Differences in effect between acupuncture and the different sham acupuncture groups are shown in Table 7. The largest difference in effect between acupuncture and sham acupuncture was seen in trials using nonpenetrating needles, whereas the smallest difference was seen in trials using needle penetration. Significant differences were found between trials using penetrating needle sham and trials that used nonpenetrating or non-needle sham (difference in SD = -.30, 95% CI = -.60 to -.00,  $P = .047$ ), although this result was sensitive to the exclusion of the outlying Vas trials<sup>89-91</sup> (difference in SD = -.07, 95% CI = -.24 to .10,  $P = .4$ , Table 8), 2 of which used nonpenetrating controls.

**No Acupuncture Control Analysis**

In addition to updating the analysis comparing types of sham acupuncture control, we also updated the analysis comparing types of no acupuncture control. We

updated the categorization of no acupuncture control groups, and categorized trials as having a high-intensity, usual care, or low-intensity control group. In a “high-intensity” control group, patients received a specified course of protocol-guided treatment. For instance, the United Kingdom Acupuncture, Physiotherapy and Exercise (APEX) trial by Foster et al<sup>33</sup> is considered a high-intensity control because patients were randomized to receive a course of individualized, supervised physical therapy plus acupuncture versus physical therapy alone. In a trial with “usual care” control, patients are able to access whatever care they might reasonably receive outside of the study. As an example, in the United Kingdom National Health Service (NHS) study, patients were randomized to “use” versus “avoid” acupuncture and could receive whatever other treatments were offered to them.<sup>95</sup> A control group was defined as “low-intensity” if patients were not allowed to receive certain treatments that might otherwise be available. For instance, the Acupuncture Randomized Trials for low back pain and osteoarthritis limited treatment of pain in the control group to oral nonsteroidal anti-inflammatory drugs (NSAIDs), excluding other types of treatment, such as

**Table 2. Primary Analyses (N = 44 Trials)**

ANALYSIS	INDICATION	STUDIES, N	SHAM			NO ACUPUNCTURE CONTROL			
			FE (95% CI)	HETEROGENEITY P	RE (95% CI)	STUDIES, N	FE (95% CI)	HETEROGENEITY P	RE (95% CI)
Main analysis	Nonspecific musculoskeletal pain	10	.30 (.21–.38)	< .001	.49 (.16–.81)	12	.54 (.50–.57)	< .001	.50 (.38–.63)
	Osteoarthritis	9	.24 (.17–.31)	< .001	.45 (.15–.75)	10	.63 (.56–.69)	< .001	.74 (.46–1.01)
	Chronic headache	5	.16 (.08–.25)	.4	.16 (.08–.25)	7	.44 (.39–.48)	< .001	.56 (.35–.76)
	Shoulder	4	.57 (.44–.69)	.4	.57 (.44–.69)	0	No trials		
Exclusion of Vas trials	Nonspecific musculoskeletal pain	9	.19 (.11–.28)	.001	.31 (.13–.48)				
	Osteoarthritis	8	.18 (.10–.25)	< .001	.35 (.07–.62)				
	Shoulder	3	.58 (.42–.74)	.2	.61 (.40–.81)				
Separate pain types	Back pain	7	.17 (.07–.26)	< .001	.30 (.08–.52)	9	.46 (.41–.50)	< .001	.52 (.37–.67)
	Neck pain	3	.83 (.64–1.01)	< .001	.82 (–.11 to 1.75)				
Excluding trials with summary data only	Nonspecific musculoskeletal pain	9	.27 (.19–.35)	< .001	.44 (.11–.78)	11	.53 (.50–.56)	< .001	.45 (.33–.57)
	Osteoarthritis	8	.19 (.12–.26)	< .001	.26 (.04–.48)	9	.59 (.52–.65)	< .001	.59 (.37–.82)
	Chronic headache					5	.43 (.38–.47)	< .001	.44 (.24–.64)
	Shoulder	3	.62 (.46–.77)	.4	.62 (.46–.77)				
Excluding trials with possible bias due to blinding	Nonspecific musculoskeletal pain	7	.28 (.19–.37)	< .001	.51 (.09–.93)				
	Osteoarthritis	9	.23 (.16–.31)	< .001	.44 (.13–.75)				
	Chronic headache*	3	.15 (.03–.26)	.15	.12 (–.05 to .29)				
Including trials with high likelihood of bias due to blinding	Osteoarthritis	10	.23 (.17–.30)	< .001	.42 (.14–.70)				
Multiple imputation	Nonspecific musculoskeletal pain	10	.29 (.21–.38)	< .001	.48 (.16–.81)	12	.54 (.50–.57)	< .001	.51 (.38–.64)
	Osteoarthritis	9	.24 (.17–.31)	< .001	.45 (.15–.75)	10	.63 (.57–.70)	< .001	.74 (.46–1.01)
	Chronic headache	5	.16 (.08–.25)	.4	.16 (.08–.25)	7	.44 (.40–.49)	< .001	.55 (.35–.75)
	Shoulder	4	.56 (.44–.69)	.4	.56 (.44–.69)				
Excluding trials in which acupuncture and control groups received additional treatments	Nonspecific musculoskeletal pain					10	.54 (.51–.57)	< .001	.54 (.40–.67)
	Osteoarthritis	4	.21 (.11–.31)	.081	.22 (.07–.38)	7	.70 (.62–.78)	< .001	.70 (.47–.93)
	Chronic headache					5	.43 (.38–.47)	< .001	.44 (.24–.64)
	Shoulder	3	.58 (.42–.74)	.2	.61 (.40–.81)				

Abbreviations: FE, fixed effects estimate; RE, random effects estimate.

NOTE. Acupuncture is superior to control at  $P < .001$  except where indicated.\* $P = .015$ .

**Table 3. Sensitivity Analyses Including Only Pain End Points Measured Between 2 and 3 Months After Randomization**

ANALYSIS	INDICATION	SHAM			No ACUPUNCTURE CONTROL				
		STUDIES, N	FE (95% CI)	HETEROGENEITY P	RE (95% CI)	STUDIES, N	FE (95% CI)	HETEROGENEITY P	RE (95% CI)
Main analysis	Nonspecific musculoskeletal pain	5	.13 (.01–.25)	.005	.23 (–.03 to .49)	9	.60 (.56–.64)	< .0001	.47 (.34–.61)
	Osteoarthritis	7	.31 (.23–.39)	< .0001	.69 (.24–1.14)	9	.73 (.66–.80)	< .0001	.88 (.61–1.15)
	Chronic headache	5	.14 (.06–.22)	.4	.14 (.06–.22)	7	.43 (.38–.47)	< .0001	.45 (.27–.63)
	Shoulder	2	No meta-analysis						

Abbreviations: FE, fixed effects estimate; RE, random effects estimate.

**Table 4. Trial-Level Acupuncture Characteristics (N = 39)**

Characteristic	n (%)
Style of acupuncture	
Combination of traditional Chinese and Western	9 (23)
Traditional Chinese techniques	23 (59)
Western	7 (18)
Point prescription	
Fixed needle formula	9 (23)
Flexible formula	18 (45)
Individualized	13 (33)
Location of needles	
Local as well as distal points	37 (95)
Distal points only	2 (5.1)
Electrical stimulation allowed	11 (28)
Manual stimulation allowed	36 (92)
Moxibustion allowed	6 (15)
Other adjunctive therapies allowed	8 (21)
De Qi attempted (n = 35)	33 (94)
Acupuncture-specific patient practitioner interactions	16 (40)
Minimum years of experience required	
No requirement specified (0 years)	14 (36)
6 Months to 2 years	7 (18)
3 to 4 Years	13 (33)
5 to 9 Years	3 (7.7)
10 Years	2 (5.1)
Maximum number of sessions	
1 to 5	3 (7.7)
6 to 10	19 (49)
11 to 15	12 (31)
16 to 20	1 (2.6)
21 to 25	2 (5.1)
26 to 30	2 (5.1)
Frequency of sessions (mean number of sessions per week)	
.88	1 (2.6)
1	19 (49)
1.43	1 (2.6)
1.5	7 (18)
1.67	1 (2.6)
2	9 (23)
5	1 (2.6)
Mean duration of sessions, rounded to whole numbers (n = 34)	
15 to 19 Minutes	1 (2.9)
20 to 24 Minutes	11 (32)
25 to 29 Minutes	6 (18)
30 Minutes or more	16 (47)
Mean number of needles used (n = 33)	
1 to 4	3 (9.1)
5 to 9	11 (33)
10 to 14	12 (36)
15 to 20	7 (21)

NOTE. Counts for point prescription sum to 40 because 1 trial had 2 acupuncture groups, with each group receiving acupuncture on the basis of a different point prescription.

steroids and other classes of analgesics.<sup>11,108</sup> Trials were assessed and assigned a control group type by 3 collaborators, with disagreements resolved by consensus. One trial was excluded from this analysis because there was a reasonable argument that it involved active control, prespecified to be excluded.<sup>26</sup> Differences in effect Appendices - Page A- 211

**Table 5. Patient-Level Acupuncture Characteristics, N = 20,827**

Characteristic	n (%)
Number of sessions	
0	441 (2.1)
1 to 5	515 (2.5)
6 to 10	8,003 (38)
11 to 15	2,065 (10)
16 to 20	40 (.2)
21 to 30	15 (<.1)
Missing	1,989 (10)
Not reported	7,759 (37)
Average session duration	
2 to 15 Minutes	163 (.8)
15 to 30 Minutes	2,668 (13)
31 to 45 Minutes	377 (1.8)
46 to 60 Minutes	25 (.1)
60 or more Minutes	1 (<.1)
Missing	896 (4.3)
Not reported	16,697 (80)
Average number of needles	
2 to 5	22 (.1)
6 to 10	910 (4.4)
11 to 15	762 (3.7)
16 to 20	825 (4.0)
21 to 25	199 (1.0)
26 or more	30 (.1)
Missing	1,621 (7.8)
Not reported	16,458 (79)
Age of physician/acupuncturist, years	
30 to 35	298 (1.4)
36 to 40	2,119 (10)
41 to 45	2,630 (13)
46 to 50	2,407 (12)
51 to 55	1,701 (8.2)
56 to 60	872 (4.2)
60 or more	303 (1.5)
Missing	368 (1.8)
Not reported	10,129 (49)
Physician/acupuncturist sex	
Female	3,626 (17)
Male	7,002 (34)
Missing	70 (.3)
Not reported	10,129 (49)

between acupuncture and no acupuncture control groups are presented in Table 7. Significant differences were found between acupuncture and control for all types of no acupuncture control group. Notably, however, in trials that had high-intensity control groups, acupuncture had smaller effect sizes compared with those with low-intensity controls groups (difference =  $-.81$ , 95% CI =  $-1.26$  to  $-.36$ ,  $P = .0004$ ); similarly, in trials with usual care control acupuncture had smaller effect sizes than trials with a low-intensity control group (difference in SD =  $-.65$ , 95% CI =  $-.98$  to  $-.31$ ,  $P = .0002$ , Table 8).

### Time Course of Acupuncture Effects Analysis

We updated a previously published analysis assessing change in the effects of acupuncture over time relative

to sham acupuncture and no acupuncture control.<sup>69</sup> Number of weeks of acupuncture treatment and the time points used in this analysis are reported in Table 9. A total of 14 trials and 4,124 patients were included in the analysis of acupuncture versus no acupuncture control. The fixed effects estimate for the between group comparison of acupuncture versus no acupuncture controls showed a decrease in the effect size of acupuncture of .019 SD per 3 months (95% CI =  $-.041$  to  $.003$ ,  $P = .096$ ,  $P = .011$  for heterogeneity, Fig 4A). With a difference between acupuncture and no acupuncture control of approximately .5 SD, this is equivalent to approximately a 15% decrease in acupuncture effect relative to control at 1 year after randomization, which was usually between 9 and 10 months after the end of treatment. In the analysis of acupuncture versus sham acupuncture, a total of 21 trials and 6,276 patients were included. There was a nonsignificant decrease of .012 SD per 3 months in acupuncture relative to sham acupuncture (95% CI =  $-.035$  to  $.011$ ,  $P = .3$ , Fig 4B), approximately a 25% decrease in acupuncture effect at 1 year after randomization. Significant heterogeneity among trials was seen ( $P < .0001$ ). The previous analysis reported that the decrease in effect of acupuncture relative to sham was driven by the decrease in neck pain trials (a decrease of .587 SD per 3 months, 95% CI =  $-.767$  to  $-.406$ ,  $P < .0001$ ). We also analyzed the change in acupuncture relative to sham excluding these trials and found a nonsignificant decrease of  $-.003$  SD per 3 months (95% CI =  $-.026$  to  $.020$ ,  $P = .8$ ) with no significant heterogeneity among trials ( $P = .12$ ). Hence almost all the decrease in acupuncture effects in this analysis seems attributable to neck pain.

As a sensitivity analysis, we repeated the analyses including only trials that reported a significant difference between acupuncture and control, because trials that showed no difference between groups cannot show a reduction in acupuncture effects over time. Nine trials with 2,997 patients were included in this analysis for the comparison between acupuncture and no acupuncture controls. A smaller and still nonsignificant decrease in the effect of acupuncture was found ( $-.008$  SD per 3 months, 95% CI =  $-.034$  to  $.018$ ,  $P = .5$ ) and heterogeneity between trials was reduced ( $P = .082$ ). None of the newly included trials showed a significant effect of acupuncture versus sham and so this analysis of sham-controlled trials with a significant effect contains the same 7 trials and 1,450 patients and has the same results as reported in the original publication ( $-.049$  SD per 3 months, 95% CI =  $-.086$  to  $-.013$ ,  $P = .008$ , heterogeneity  $P < .0001$ ).

### Discussion

We updated an individual patient data meta-analysis of high-quality trials of acupuncture for chronic pain with 7 additional years of data. An additional 10 studies were included with nearly 3,000 patients. In total, our analyses include 39 studies and 20,827 patients. The results confirm and strengthen previous key findings that acupuncture has a clinically relevant effect compared with

**Table 6. Results of Univariate Metaregression Analyses for the Effect of Acupuncture Characteristics on Acupuncture Effect**

CHARACTERISTIC	SHAM ACUPUNCTURE				NO ACUPUNCTURE CONTROL			
	TRIALS, N	B	95% CI	P	TRIALS, N	B	95% CI	P
Style of acupuncture	25				25			
Some TCM versus Western only		-.00	-.49 to .48	>.9		.10	-.55 to .74	.8
TCM only versus some Western		.02	-.38 to .42	.9		-.07	-.42 to .28	.7
Point prescription	25				25			
Fixed needle formula		Reference		.6		Reference		.075
Flexible formula		.20	-.21 to .60			.01	-.45 to .46	
Fully individualized		-.01	-.75 to .73			-.34	-.79 to .10	
Electrical stimulation allowed	25	.32	-.11 to .75	.14	25	-.12	-.50 to .26	.5
Manual stimulation allowed	25	.26	-.42 to .95	.5	25	-.38	-.99 to .23	.2
Moxibustion allowed		No trials allowed			25	-.32	-.71, .06	.10
Other adjunctive treatment allowed	25	-.04	-1.00 to .92	.9	25	-.22	-.59 to .16	.3
De qi attempted	25	.29	-.67 to 1.24	.6	21	.74	-.04 to 1.52	.063
Acupuncture-specific patient practitioner interactions allowed	25	-.03	-.50 to .44	.9	25	-.05	-.38 to .28	.8
Minimum years of experience required	25	.04	-.05 to .13	.4	25	.05	-.03 to .12	.2
Maximum number of sessions (per 5 sessions)	25	-.01	-.23 to .22	.9	25	.01	-.12 to .14	.9
Patient-level analysis	5 (1,317/1,377)	.09	-.31 to .48	.7	5 (8,036/10,157)	.10	-.01 to .21	.001
Patient-level analysis, including Hinman et al <sup>39</sup>	6 (1,421/1,517)	-.03	-.36 to -.30	.9				
Frequency of sessions (per week)	25	-.06	-.29 to .18	.6	25	.21	-.22 to .64	.3
Duration of sessions (per 5 minutes)	25	.06	-.13 to .25	.5	20	-.06	-.25 to .13	.5
Patient-level analysis	6 (2,863/2,969)	.01	-.08 to .09	.9				
Number of needles used (per 5 needles)	25	.05	-.17 to .27	.6	19	.16	-.05 to .38	.13
Patient-level analysis	5 (2,232/2,317)	.04	-.08 to .16	.5				
Age of practitioner (per 5 years)					6 (9,127/10,550)	-.01	-.04 to .02	.5
Patient-level analysis								
Male practitioner					6 (9,384/10,550)	-.07	-.16 to .02	.084
Patient-level analysis								

Abbreviation: TCM, traditional Chinese medicine.

NOTE.  $\beta$  is an estimate of the change in the effect of acupuncture in terms of standardized difference compared with controls for each characteristic; a positive  $\beta$  indicates a larger effect of acupuncture compared with controls for trials. The number of patients in the analysis and number of patients in included trials are given in parentheses where applicable.

no acupuncture control. Moreover, we confirmed that, although the effects of acupuncture are not completely explicable in terms of placebo effects, factors other than the specific effects of needling at correct acupuncture point locations are important contributors to acupuncture treatment benefit. Effects of acupuncture appear to persist over at least a 12-month period.

Heterogeneity continues to be an obvious aspect of our findings, with the results of trials varying by more than would be expected by chance. We have presented data that heterogeneity is predominately driven by differences between control groups rather than by differences between acupuncture treatment characteristics. We did not find any obvious differences between the results of trials depending on treatment characteristics such as style of acupuncture, duration of treatment sessions, or training of acupuncturists. In contrast, we found evidence that effect sizes of acupuncture were smaller for sham-controlled trials with penetrating needles and for no acupuncture controlled trials in which patients received

high-intensity care (eg, a trial of acupuncture plus physical therapy vs physical therapy alone). In some cases, heterogeneity was also driven by a set of outlying trials with large effect sizes. We have presented these analyses with and without the outlying trials to provide all necessary information for interpreting these results and drawing conclusions.

Another novel finding is the higher than average effects of acupuncture on upper body musculoskeletal pain. We now have sufficient data to conduct a meta-analysis for neck pain and for shoulder pain, even after exclusion of outlying trials. The effect sizes versus sham, .57 for shoulder and .83 for neck pain, were much larger than for low back pain, osteoarthritis, and headache, although we also saw evidence that treatment benefits did not persist for neck pain.

Since publication of our results, there has been no substantive critique of our methodology in the peer-reviewed literature. The main issue under discussion seems to be whether the effect size of acupuncture is

**Table 7. Differences in Effect Size (in SD) Between Acupuncture and Sham Acupuncture Groups (n = 25) and Between Acupuncture and No Acupuncture Control Groups (n = 24)**

	N	EFFECT SIZE (95% CI)	P
<i>SHAM ACUPUNCTURE, TYPE OF CONTROL GROUP</i>			
Penetrating needle sham	11	.17 (.11-.22)	<.0001
Excluding B blinding grades	9	.16 (.09-.24)	<.0001
Nonpenetrating needle and non-needle sham	15	.48 (.22-.74)	.0003
Excluding B blinding grades	11	.51 (.16-.86)	.004
Including Hinman et al <sup>39</sup>	16	.46 (.21-.70)	.0003
Excluding Vas trials <sup>89-91</sup>	12	.27 (.10-.44)	.002
Nonpenetrating needle sham	10	.52 (.14-.91)	.007
Excluding Vas trials <sup>89-91</sup>	7	.22 (-.05-.49)	.11
Non-needle sham	5	.37 (.21-.52)	<.0001
Including Hinman et al <sup>39</sup>	6	.32 (.18-.46)	<.0001
True acupuncture points (no penetrating needle sham)	12	.48 (.15-.80)	.004
Excluding B blinding grades	10	.51 (.12-.89)	.010
Including Hinman et al <sup>39</sup>	13	.45 (.15-.75)	.003
Excluding Vas trials <sup>89-91</sup>	10	.25 (.06-.44)	.011
Nonacupuncture points (no penetrating needle sham)	3	.52 (.35-.69)	<.0001
Excluding Vas trials <sup>90</sup>	2	.47 (.13-.81)	.007
<i>NO ACUPUNCTURE CONTROL, TYPE OF CONTROL GROUP</i>			
High-intensity	5	.34 (.11-.57)	.003
Usual care and low-intensity	19	.56 (.43-.69)	<.0001
Usual care	17	.50 (.40-.60)	<.0001
Low-intensity	2	1.14 (.71-1.58)	<.0001

NOTE. Total number of sham acupuncture-controlled trials sums to 26 because 1 trial had 2 different types of sham acupuncture control.

clinically relevant,<sup>94</sup> specifically, whether clinical relevance is determined by the comparison with no acupuncture control or by comparison with sham. We have previously argued in favor of the former, on the grounds that the clinical decision made by a referring clinician in discussion with their patient is not between acupuncture and sham but between acupuncture and no acupuncture. Our argument is given the context of the excellent safety profile of acupuncture,<sup>65</sup> evidence that the nonspecific effects of acupuncture are particular to acupuncture and are not easily reproduced,<sup>46,54</sup> and evidence provided here and elsewhere<sup>9</sup> that some interventions used as sham acupuncture may be physiologically active.

It is also illustrative to compare our results with those of other interventions routinely used in clinical practice. For instance, in one meta-analysis of NSAIDs for osteoarthritis of the knee, the effect size for NSAIDs versus placebo for trials that did not preselect NSAID responders was .23<sup>10</sup>; for chronic low back pain, the effect size for NSAIDs was < .20.<sup>29</sup>

We find several implications for research. In terms of the methodology of subsequent acupuncture trials for chronic pain, we find that the balance of evidence is to give a higher dose of acupuncture in terms of a greater number of treatments in trials without sham control. Although the nature of the control group in trials will naturally be driven by the research question, investigators should be aware of the evidence that control arms that incorporate a relatively intense level of intervention, such as when acupuncture is added into an intensive rehabilitation regimen, tend to lead to smaller effect sizes, as do sham controls that involve needle penetration. Further research is warranted on whether acupuncture is particularly effective for upper body musculoskeletal

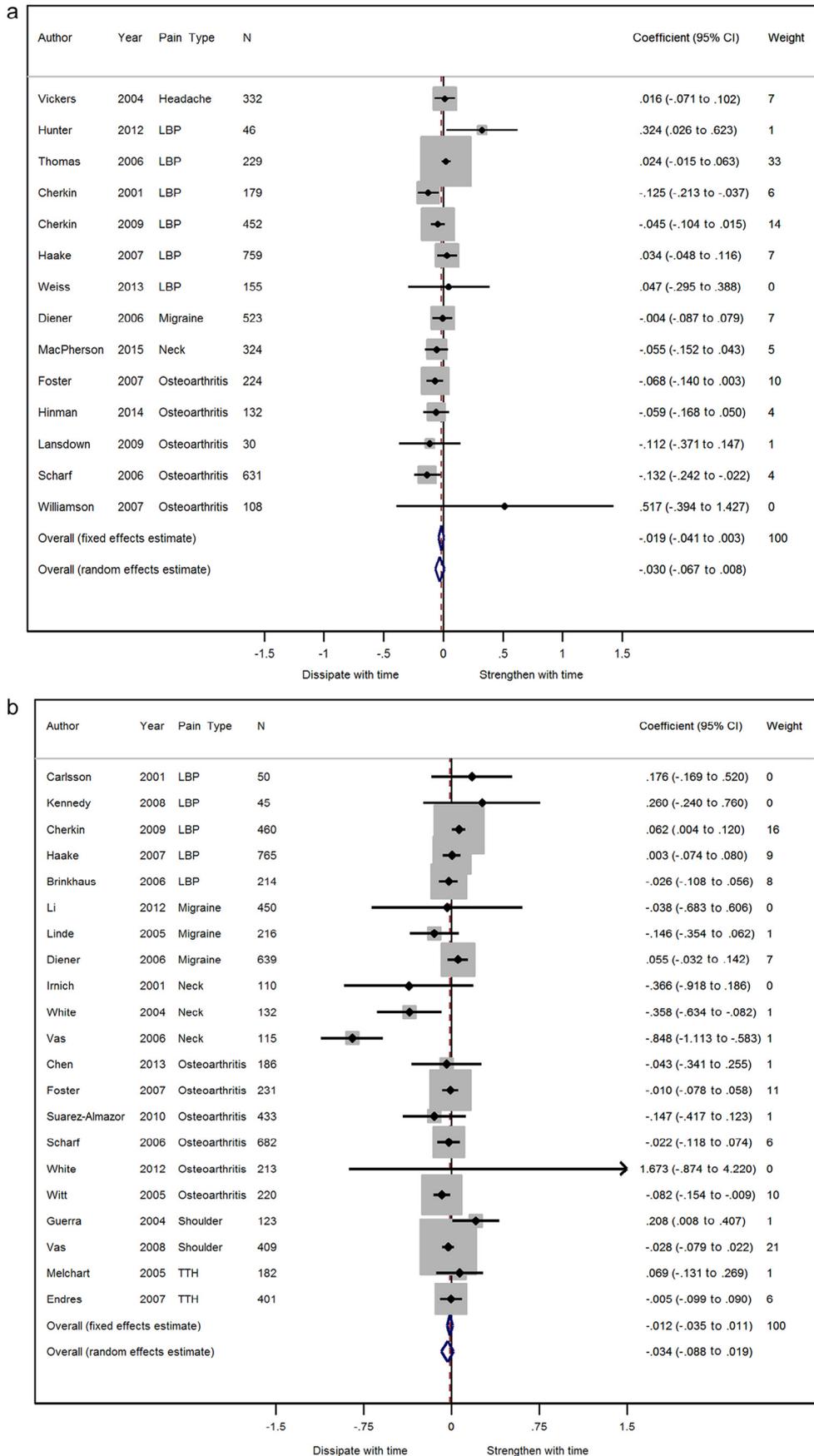
**Table 8. Differences in Effect Size Between Different Types of Control Group**

GROUP 1	GROUP 2	EFFECT SIZE (95% CI)	P
<i>SHAM ACUPUNCTURE</i>			
Penetrating needle sham	Nonpenetrating and non-needle sham	-.30 (-.60 to -.00)	.047
Excluding B blinding grades		-.33 (-.72 to .05)	.088
Including Hinman et al <sup>39</sup>		-.28 (-.57 to .01)	.061
Excluding Vas trials <sup>89-91</sup>		-.07 (-.24 to .10)	.4
Nonpenetrating needle sham	Non-needle sham	.13 (-.44 to .70)	.6
Including Hinman et al <sup>39</sup>		.18 (-.34 to .70)	.5
Excluding Vas trials <sup>89-91</sup>		-.18 (-.52 to .17)	.3
True acupuncture points, excluding penetrating needle sham	Non-acupuncture points to excluding penetrating needle sham	-.02 (-.70 to .66)	.9
Including Hinman et al <sup>39</sup>		-.05 (-.71 to .61)	.9
Excluding Vas trials <sup>89-91</sup>		-.22 (-.75 to .30)	.4
<i>NO ACUPUNCTURE CONTROLS</i>			
High-intensity	Usual care and low-intensity	-.23 (-.50 to .05)	.11
High-intensity	Low-intensity	-.81 (-1.26 to -.36)	.0004
Usual care	Low-intensity	-.65 (-.98 to -.31)	.0002

NOTE. A negative effect size indicates that there is a smaller difference in effect between acupuncture and control for group 1 than for group 2, for instance, the effect of control group 1 is more similar to verum acupuncture than the effect of control group 2.

**Table 9. Trials With Sham and No Acupuncture Control and Time Points Assessed After the End of Treatment**

REFERENCE	PAIN CONDITION	AVERAGE LENGTH OF TREATMENT, WEEKS	TIME POINTS AFTER END OF TREATMENT	SHAM ACUPUNCTURE		NO ACUPUNCTURE CONTROL	
				INCLUDED IN META-ANALYSIS	CONTROL PATIENTS OFFERED ACUPUNCTURE TREATMENT (CROSSOVER)	TIME POINTS AFTER END OF TREATMENT	INCLUDED IN META-ANALYSIS
Carlsson et al <sup>13</sup>	Low back pain	8	Weeks 5 and 18	Yes			
Chen et al <sup>16</sup>	Osteoarthritis	12	End of treatment and week 14	Yes			
Endres et al <sup>28</sup>	Headache	6	End of treatment and weeks 7 and 20	Yes			
Guerra de Hoyos et al <sup>35</sup>	Shoulder	8	Weeks 5 and 18	Yes			
Irnich et al <sup>41</sup>	Neck	3	Weeks 1 and 10	Yes			
Kennedy et al <sup>48</sup>	Low back pain	5	End of treatment and week 7	Yes			
Kerr et al <sup>49</sup>	Low back pain	6	None	No			
Kleinhenz et al <sup>52</sup>	Shoulder	4	End of treatment	No			
Li et al <sup>59</sup>	Migraine	4	End of treatment and week 4	Yes			
Vas et al <sup>89</sup>	Osteoarthritis	12	Week 1	No			
Vas et al <sup>91</sup>	Neck	3	Weeks 1 and 25	Yes			
Vas et al <sup>90</sup>	Shoulder	3	Weeks 1 and 10	Yes			
White et al <sup>104</sup>	Neck	4	End of treatment and weeks 1 through 8	Yes			
White et al <sup>103</sup>	Osteoarthritis	4	End of treatment and week 1	Yes			
Berman et al <sup>8</sup>	Osteoarthritis	26	End of treatment	No	No	End of treatment	No
Brinkhaus et al <sup>11</sup>	Low back pain	8	End of treatment and weeks 18 and 44	Yes	At 8 weeks	End of treatment	No
Cherkin et al <sup>19</sup>	Low back pain	7	Weeks 1, 19, and 45	Yes	No	Weeks 1, 19, and 45	Yes
Diener et al <sup>26</sup>	Migraine	6	End of treatment and weeks 7 and 20	Yes	No	End of treatment and weeks 7 and 20	Yes
Foster et al <sup>33</sup>	Osteoarthritis	3	Weeks 3, 23, and 49	Yes	No	Weeks 3, 23, and 49	Yes
Haake et al <sup>36</sup>	Low back pain	6	End of treatment and weeks 7 and 20	Yes	No	End of treatment and weeks 7 and 20	Yes
Linde et al <sup>63</sup>	Migraine	8	End of treatment and weeks 4 and 16	Yes	At 12 weeks	Week 4	No
Melchart et al <sup>71</sup>	Headache	8	End of treatment and weeks 4 and 16	Yes	At 12 weeks	Week 4	No
Scharf et al <sup>80</sup>	Osteoarthritis	6	Weeks 7 and 20	Yes	No	Weeks 7 and 20	Yes
Suarez-Almazor et al <sup>85</sup>	Osteoarthritis	6	End of treatment and week 7	Yes	No	Week 7	No
Witt et al <sup>108</sup>	Osteoarthritis	8	End of treatment and weeks 18 and 44	Yes	At 8 weeks	End of treatment	No
Cherkin et al <sup>18</sup>	Low back pain	10			No	End of treatment and week 42	Yes
Hinman et al <sup>39</sup>	Osteoarthritis	12			No	End of treatment and week 40	Yes
Hunter et al <sup>40</sup>	Low back pain	6			No	Weeks 2, 7, and 20	Yes
Jena et al <sup>43</sup>	Headache	12			At 12 weeks	All measurements after crossover	No
Lansdown et al <sup>56</sup>	Osteoarthritis	10			No	Weeks 3 and 42	Yes
MacPherson et al <sup>67</sup>	Neck	16			No	Weeks 10 and 36	Yes
Thomas et al <sup>87</sup>	Low back pain	12			No	Weeks 1, 40, and 92	Yes
Salter et al <sup>79</sup>	Neck	12			No	Week 1	No
Vickers et al <sup>95</sup>	Headache	6			No	Weeks 1 and 40	Yes
Weiss et al <sup>102</sup>	Low back pain	4			No	End of treatment and week 13	Yes
Williamson et al <sup>107</sup>	Osteoarthritis	6			No	Weeks 1 and 6	Yes
Witt et al <sup>109</sup>	Neck	12			At 12 weeks	All measurements after crossover	No
Witt et al <sup>110</sup>	Osteoarthritis	12			At 12 weeks	All measurements after crossover	No
Witt et al <sup>111</sup>	Low back pain	12			At 12 weeks	All measurements after crossover	No



**Figure 4.** Forest plot showing the difference in pain change scores between acupuncture and no acupuncture control groups (A) and between acupuncture and sham acupuncture groups (B) over time. A coefficient of .01 means that the difference between acupuncture and control increases by .01 SD for each 3 months after the end of treatment.

pain. An associated hypothesis is whether there are subtypes of other chronic pain indications that have differential response to acupuncture. It would naturally be ideal to know before referring a patient for treatment whether, say, the type of back pain they are experiencing is one that would be amenable to treatment with acupuncture. We will also repeat our previous call for research on how best to incorporate acupuncture into the multidisciplinary care of chronic pain patients.

## Conclusions

We have confirmed that acupuncture has a clinically relevant, persistent effect on chronic pain that is not completely explained by placebo effects. Referral for a course of acupuncture treatment is therefore a reasonable option for a patient with chronic pain.

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## Supplementary Data

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## **Appendix D**

### **Public Hearing Summary and Follow Up**

August 2, 2019 Public Hearing  
Participants

**Applicant Group Presenters:**

- Ash Goddard, DACM, LAc. - presented on dry needling, trigger points and more
- Carly Samish, LAc, LMT - presented on Japanese needles
- Charis Wolf, AEMP, WAEMA President - presented on auricular-ear acupuncture
- Barbara Paul-Mayer, AEMP, Mac - presented on substance abuse disorder
- Susan Shultz, AEMP, D.C. - presented on point injection therapy substances

**Public Participants**

Name	Representing	Position on Proposal	Testified
Susanne Michaud	Self	Oppose	Yes
Jana Wiley	Acupuncturist/RN	In Favor	Yes
George Whiteside	AEMP's	In Favor	Yes
Catherine Dayhoff	Acupuncture	In Favor	Yes
Jamil Shoot	Acupuncture	In Favor	Yes
Teri Manley	Acupuncture	In Favor	Yes
Nick Spurlock	Acupuncture	In Favor	Yes
Melissa Johnson	Physical Therapy Association of Washington (PTWA)	Oppose	Yes
Ben Boyle	PTWA/PPSIG	Oppose	No
Leslie Emerick	WAEMA	In Favor	Yes
Jeb Shepard	WSMA	In Favor	Yes
Jackie Barry	PTWA	Oppose	No
Barbara Paul	Washington acupuncture and Eastern Medicine Assoc. (WAEMA)	In Favor	Yes
Zack Rayburn	PTWA	Oppose	No
Brad Tower	WANP		No
Danielle Fredericks	PTWA	Oppose	No
Robert May	WA Association of Naturopathic Physicians	Concerns	Yes
Megan Thomas, PT, DPT	PTWA	Concerns	No
Nicholas Hamley, PT, DPT, MPT	PTWA	Concerns	No

2019 Acupuncture Scope of Practice Sunrise  
Summary of Public Hearing  
August 2, 2019

The applicant group presented their applicant report for the sunrise proposal. There were five presenters and their presentations follow.

**Sunrise Review Testimony**

2 August 2019

*Submitted by*

**Ash Goddard, DACM, L.Ac.**

Doctor of Acupuncture & Chinese Medicine, Diplomate of Acupuncture (NCCAOM)

Diplomate of Chinese Herbology (NCCAOM)

Former president of Washington Acupuncture & Eastern Medicine Association (WAEMA)

Instructor of Acupuncture Orthopedics at Middle Way Acupuncture Institute

*Introduction*

In our applicant report we proposed that the current definition of what is considered acupuncture is not clear enough for the general public and additional clarification is needed to assure that citizens and even allied health providers understand the depth and breadth of the practice of acupuncture. There is overlap and potential confusion over the insertion of acupuncture (filiform) needles for therapeutic purposes with other professions using different terminology for the same procedures we perform. The written comments that were submitted prior to the hearing reflect the very misunderstanding of both our training and the modern practice of acupuncture that we want to clarify with this Sunrise.

In keeping with RCW 18.120.030, a profession must be regulated to ensure public safety and also to inform consumers in identifying competent practitioners. So, a potential harm to the public exists not simply when practitioners are not adequately trained or licensed but also when a consumer becomes confused about what kind of treatment they are receiving.

This prompts us to reconcile the legal with the contemporary definitions of treatments we offer and to increase an understanding of our practice. This scope clarification is not intended to limit other professions from gaining access legislatively to acupuncture techniques with appropriate training and regulation, but rather assures that these terms will *also* be understood as the practice of acupuncture, not to be superseded or disallowed by alternative definitions that may arise in the future.

Our proposal includes updating language that reflects the modern practice of acupuncture and the inclusion of commonly used terms for various procedures we already perform that are well within our scope. This proposed language is appropriate and in keeping with current acupuncture training and practice. I believe you have the language in front of you. The various “modern” terms that are ubiquitous in acupuncture practice today including: “motor points, trigger points, intramuscular needling, dry needling.”

When the language of our scope was written and even re-written, no one in our profession had the foresight to predict the dramatic increase in not only the interest in acupuncture treatment but also the interest on behalf of other professions in the practice of acupuncture and related techniques utilizing a filiform needle. We recognize that creating a clearer understanding of what we as acupuncturists do is imperative.

*Acupuncture in the West*

Outlining the trajectory of acupuncture and also dry needling, in the West is valuable here. The practice of acupuncture in the West has grown exponentially over the last several decades. Its increasingly proven effectiveness for pain relief and other ailments have taken from it from an alternative treatment to being

included in our insurance plans and even mainstream clinics and hospitals. Since the 1950s, Chinese scholars and later many others in the West began to seek an explanation of acupuncture that was in keeping with modern scientific principals and that knowledge has steadily been integrated in acupuncture practice worldwide.<sup>1</sup>

From a related western trajectory, it was in 1976 that Dr. Chan Gunn, a physician in British Columbia who later worked at the University of Washington and originated the term “intramuscular stimulation,” wrote in an article titled, “Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Known Neural Structures.” He wrote, “It is suggested that, as a first step towards the understanding and acceptance of acupuncture by the medical profession, the present anachronistic systems of acupuncture locus nomenclature be dispensed with in favour of a modern, scientific one using neuroanatomic descriptions.”<sup>2</sup> He relabeled many acupuncture points as such, which are in the appendix of the paper I have submitted. I don’t fault his intent—the layperson and other medical providers struggle to understand acupuncture today simply because they do not have the training to comprehend the underlying theory and methodology. Framing these concepts in a language we in the West can understand did and still does make acupuncture more accessible.

Indeed, the acupuncture profession—particularly the cohort focused on orthopedics and pain management—has embraced these neuroanatomic descriptions but *not* at the expense of the ancient theory and practice. That is, a neuroanatomic model is valuable and useful and can certainly inform modern practice and inter-disciplinary communication, yet it is incomplete to base modern acupuncture practice solely on that explanation.

#### *Trigger Points and Motor Points*

The WAC created through our Point Injection Therapy rulemaking established a precedent in Washington law for the use of the phrase “trigger points as a subset of acupuncture points and Ashi points as recognized in the current practice of East Asian medicine.” (WAC 246-803-030 (10)(b).

It is an interesting position to be in to argue that something so inherent in the practice of our medicine is indeed within our scope. I was looking back at an article I wrote that was published in the *Journal of Chinese Medicine* in which I advise practitioners to use a “lifting and thrusting technique similar to trigger point needling.”<sup>3</sup> No further explanation was required because I knew the reader—an acupuncturist—would know what I was referring to. Nevertheless, it may be useful to survey the language and history of what we now call trigger point needling by its many names, including dry needling and intramuscular needling or intramuscular stimulation.

*History of trigger points and motor points themselves.* The overlap between these structures and acupuncture points has been studied for decades. We’ve made these points several times before via the Sunrise review process when PTs were attempting their scope expansion and we’ve also submitted them in writing in this Sunrise process. They include:

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<sup>1</sup> White A, Ernst E. (2004). A brief history of acupuncture. *Rheumatology*. 43(5): 662–3 [PubMed] [Google Scholar]

<sup>2</sup> Gunn, C. Chan. (1976). “Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Known Neural Structures.” *American Journal of Chinese Medicine* 4.No. 2:183.

<sup>3</sup> Goddard, A. (2011). “The Runner’s Point: An Extra Point for Treatment & Prevention of Lower Leg Injuries.” *Journal of Chinese Medicine*. 97:25-28.

- Ronald Melzack, Ph.D., world-renowned pioneer in the field of pain research, reported that, “trigger points and acupuncture points for pain [i.e. ashi points], though discovered independently, and labeled differently, represent the same phenomenon and can be explained in terms of the same neural mechanisms.”<sup>4</sup>
- In describing needling trigger points, a 2010 study stated, “[a] very similar method was developed in 7th century by Chinese physician Sun Su-Mo [Sun Simiao], who inserted needles at points of pain, which he called Ah-Shi [ashi] points. From the description of these points, it is clear that they are what are currently referred to as MTrPs [Myofascial Trigger points].”<sup>5</sup>
- In 2008, two medical doctors, Dorsher and Fleckenstein, demonstrated that 93.3% of the “common trigger points” in Travell’s *Trigger Point Manual* corresponded anatomically to established classical, channel- based acupuncture points and concluded that trigger points and acupuncture points are likely the same physiologic phenomenon.<sup>6</sup>
- The World Health Organization defines trigger points as a subset of acupuncture points.<sup>7</sup>

Additional references include:

- David Legge’s article, “A History of Dry Needling,” mentions a 1941 paper correlating “... simple needling without the injection of any substance,” to prior acupuncture practice, citing acupuncture publications from 1821 and 1828.<sup>8</sup>
- Other research clearly correlated trigger points and acupuncture points as early as the 1960s and 1970s.<sup>9</sup>
- Chan Gunn also claimed in 1998, “These [acupuncture] points usually coincide with palpable, muscle bands (sometimes called trigger points) that are tender to digital pressure...”<sup>10</sup>
- Travell/Simons, authors of the *Trigger Point Manual*, later and more famously acknowledged acupuncture’s crossover with trigger point needling. In Part 1 of the 1999 edition, the authors state: “In conclusion, frequently the acupuncture point selected for the treatment of pain is actually a TrP [trigger point].”<sup>11</sup>

My primary mentor, Whitfield Reaves, met and studied with Dr. Travell in 1983 when he was teaching at a California acupuncture school. Reaves claims that he and his colleagues were the first to discuss with Travell the use of an acupuncture needle in treating trigger points. They went on to take this more refined, anatomically articulate concept of trigger points into the curricula at schools in California, New Mexico, and Colorado throughout the 1980s and 90s. I began my master’s in acupuncture program in 1997 where Reaves was teaching and eventually assisted teaching in his sports acupuncture apprenticeship program. I currently teach a variation of his program at Middle Way. We have also submitted syllabi from Washington acupuncture schools that reflect their own training in trigger point needling.

<sup>4</sup> Melzack, R, Stillwell, DM, Fox, EJ. Trigger Points and Acupuncture Points for Pain: Correlations and Implications. *Pain*. 1977;3(1):3–23.

<sup>5</sup> Kalichman L, Vulfsons S. (2010). Musculoskeletal Pain, *Journal of the American Board of Family Medicine*; 23(5): 640-646.

<sup>6</sup> Dorsher PT, Fleckenstein J. (2008). Trigger Points and Classical Acupuncture Points, Part 1: Qualitative and Quantitative Anatomic Correspondences. *German Journal of Acupuncture and Related Techniques*;51(3): 15-24

<sup>7</sup> Hoyt, J. (2012). “Acupuncture, Dry Needling and Intramuscular Manual Therapy: Understanding Acupuncture’s Therapeutic Role in America.” Coalition for Safe Acupuncture Practice. Abstract. CCAM Research Partners Press

<sup>8</sup> Legge, D. (2014). *J Musculoskeletal Pain*. DOI: 10.3109/10582452.2014.883041

<sup>9</sup> Lu, D.P., & Lu, G.P. (2013). An Historical Review and Perspective on the Impact of Acupuncture on U.S. Medicine and Society. *Medical Acupuncture*, 25(5), 311–316. doi:10.1089/acu.2012.0921

<sup>10</sup> Gunn, C. (1998). “Acupuncture and the Peripheral Nervous System A Radiculopathy Model.” Retrieved on July 28, 2019, from <http://www.istop.org/papers/Acupuncture.pdf>

<sup>11</sup> Simons, D.G., Travell, J.G., Simons, L.S. (1999). Part I: Introduction. *Travell & Simons’ Myofascial Pain and Dysfunction: The Trigger Point Manual*. P.42.

Travell later met and worked with acupuncturist and Tri-State College (of acupuncture) founder Mark Seem, PhD, LAc, in 1991 and 1992. He noted at that time, "To me, the famous classical acupuncture dictum that states, 'Where there is no free flow, there is pain,' is a description of something identical to Dr. Travell's trigger points. Because of this, I believe that tender, *a shi* points are the primary points in the treatment of pain."<sup>12</sup> "Ashi" translates roughly as "there it is." A very good example of how *ashi* points including trigger points are used in clinical practice today is in the article by Andrew Nugent-Head (submitted).<sup>13</sup> David Legge, osteopath and acupuncturist, also heavily references trigger points through his book on the treatment of the muscular system.<sup>14</sup>

Across professions, the phenomenon of a twitch response is often discussed in the treatment of trigger points. In 1993, Seem equated the well-known muscle twitch response as discussed in modern trigger point needling with the acupuncture response known as *de qi*. "When a needle succeeds in creating the celebrated *de qi* response indicating the "arrival of *qi*," the needle has actually caused a myofascial response, whereby the muscle underlying the needle begins to contract and "grasp" the needle."<sup>15</sup>

A 2003 job analysis report by the NCCAOM (the national certifying body for acupuncture standards which administers board exams and board certification), confirmed this practice as well, with 82% of acupuncturists surveyed reporting the use of trigger points in the treatment of pain.<sup>16</sup> That was 16 years ago—I would venture to guess that if that survey was performed again today, that statistic would be even higher.

*Motor points.* We also intend to add the phrase "motor points" to our scope language, and indeed a similar case can be made for these structures, where a motor nerve enters the muscle. As early as 1976, these structures were correlated to acupuncture points by Chan Gunn.<sup>17</sup> Matt Callison, former long-time instructor at Pacific College of Oriental Medicine, refined the teaching of motor point acupuncture over many years via his Sports Medicine Acupuncture program and his broadly used manual, "The Motor Point Index"<sup>18</sup>. In fact, the use of motor points, trigger points, and segmental points known as Hua Tuo Jia Ji points (named by physician Hua Tuo (110-207 CE) predates Gunn's nearly identical segmental approach by nearly two thousand years.

One may then wonder why acupuncturists prefer to use the term *ashi* points vs these modern terms. It is imperative to the integrity of acupuncture to honor the roots of the medicine and not simply swap out ancient terms for modern ones—particularly because the modern terms often leave out the larger concepts that allows a practitioner to understand and apply acupuncture theory. It is far more challenging to describe an ailment in its historical terminology such as "cold bi syndrome" than to simply tell them I am

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<sup>12</sup> Seem, Mark. (2013). "A New American Acupuncture: Acupuncture Osteopathy - The Myofascial Release of the Bodymind's Holding Patterns."

<sup>13</sup> Nugent-Head, A. (2013). "Ashi Points in Clinical Practice." *Journal of Chinese Medicine*. 101:5-12.

<sup>14</sup> Legge, D. (2010). *Jing Jin: Acupuncture treatment of the muscular system using the meridian sinews*.

<sup>15</sup> Seem, Mark. (2013). "A New American Acupuncture: Acupuncture Osteopathy - The Myofascial Release of the Bodymind's Holding Patterns."

<sup>16</sup> Fabrey, L, Cogdill, K, Kelley, J. (2003). *A National Job Analysis: Acupuncture and Oriental Medicine Profession*. Olathe, Kansas: Applied Measurement Professionals, Inc. [http://www.nccaom.org/wp-content/uploads/pdf/NCCAOM\\_final\\_JA\\_Report\\_2003.pdf](http://www.nccaom.org/wp-content/uploads/pdf/NCCAOM_final_JA_Report_2003.pdf)

<sup>17</sup> "It was noted that many of these [acupuncture] loci (35) were located at known sites of muscle motor points. These were classified as Type I." "In this study, Type I loci were demonstrated to be muscle motor points by evoking muscle twitches in response to minimum electrical stimulation using a standard calibration-stable stimulator with variable control of output." Gunn, C. Chan. (1976). "Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Known Neural Structures." *American Journal of Chinese Medicine* 4.No. 2:183.

<sup>18</sup> Callison, M. "Motor Point Index." Retrieved from Apple [electronic] Books. <https://books.apple.com/us/book/motor-point-index/id545804483>

addressing a trigger point. In modern practice, we need to communicate in both languages and have a scope that covers us appropriately.

### *Dry Needling*

The phrase “dry needling” which is actually a bit of a misnomer in and of itself. It originally referred to the needling of a trigger point with an empty—hence “dry”—hypodermic needle as opposed to one that injects an anesthetic like lidocaine. Only much later was the term “dry needling” applied to needling trigger points with an acupuncture needle. This is potentially confusing for the public and indeed the very fact that there are countless articles published on the differences between dry needling and acupuncture highlights public confusion on the matter.

Current definitions include the following, “[dry needling is] an invasive procedure in which a solid filament needle [an acupuncture needle] is inserted into the skin and muscle directly at a myofascial trigger point. A myofascial trigger point consists of multiple contraction knots, which are related to the production and maintenance of the pain cycle.”<sup>19</sup> Note that one could replace the term “dry needling” with the word acupuncture and the definition remains true.

We can actually look to the PT Dry Needling Sunrise review as laying much of the groundwork for this discussion today. In the final Sunrise report, the Department of Health acknowledged that acupuncturists assess trigger points.<sup>20</sup> Jan Dommerholt, owner of Myopain Seminars in Maryland and claims to be the first to teach dry needling to PTs,<sup>21</sup> testified that day, “There is no question about it that acupuncturists can do this and it’s in the scope.”<sup>22</sup> Dommerholt has elsewhere written,

- “Many practitioners of Acupuncture use several TrP [Trigger Point] criteria to locate pain Acupuncture points and, in fact, are successfully performing dry needling of TrPs that they speak of as Acupuncture therapy.”<sup>23</sup>
- “Manual physical therapists must realize that dry needling is also within the scope of acupuncture practice. Statements that dry needling would not be in the scope of acupuncture are inaccurate and counterproductive and not based on accurate knowledge of contemporary acupuncture practice.”<sup>24</sup>

Acupuncture nomenclature is also used in dry needling research.<sup>25</sup> Some training companies even use acupuncture points in dry needling training. It should be indisputable then that dry needling would be

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<sup>19</sup> Dommerholt J. Dry needling-IMS, FAQ. [http://www.bethesdaphysiocare.com/pdf/faq\\_dryneedling.pdf](http://www.bethesdaphysiocare.com/pdf/faq_dryneedling.pdf) Accessed September 26, 2018.

<sup>20</sup> “It appears that the overlapping skills/knowledge that are relevant in the comparison [of dry needling] with acupuncture training include palpating trigger points, physiological responses, contraindications and precautions...” and so forth. Washington State Department of Health Sunrise Review. (2016). P.15.

<http://www.doh.wa.gov/Portals/1/Documents/2000/DryNeedlingFinal2016.pdf>

<sup>21</sup> “Dry Needling: Getting to the Point.” PT in Motion website. Retrieved on July 28, 2019 from <https://www.apta.org/PTinMotion/2015/5/DryNeedling/>

<sup>22</sup> Dommerholt, J. (2 August 2016). Sunrise Review Hearing. (00:41:45) Washington Department of Health.

<sup>23</sup> Dommerholt, Jan. “Dry Needling in Orthopaedic Physical Therapy Practice.”

[Http://www.bethesdaphysiocare.com/professionals/pdf/optp\\_dryneedling\\_dommm.pdf](http://www.bethesdaphysiocare.com/professionals/pdf/optp_dryneedling_dommm.pdf). Web. 28 Dec. 2011.

<sup>24</sup> Dommerholt J. (2011). Dry needling - peripheral and central considerations. The Journal of manual & manipulative therapy, 19(4), 223–227. doi:10.1179/106698111X13129729552065

<sup>25</sup> Dunning, J. (2016). Letter submitted to and published in the Washington State Department of Health Sunrise Review, 2016. P.402. <http://www.doh.wa.gov/Portals/1/Documents/2000/DryNeedlingFinal2016.pdf>

within the scope of acupuncture and that terms such as trigger points are appropriate for acupuncturists to use in both scope description and practice.

### *Trigger point needling and CPT coding*

The American Medical Association (AMA) controls the creation of new CPT codes that are required for insurance billing. Last year the committee deliberated over adding codes for trigger point acupuncture and also for dry needling. The CPT panel concluded that a single new code will be created that will cover “needle insertion(s) without injection(s)” or retention.<sup>26</sup> The forthcoming code for trigger point needling is a sub-category of a procedure we already have in our scope, point injection therapy also known as trigger point injection. (Note that a subsequent request for the CPT panel to reconsider this matter was rejected in February of this year.<sup>27</sup>)

In summary, the terminology we are requesting be added to our scope language is appropriate, well-established in our practice and training, and undeniably within our scope already. Using these terms is not a scope expansion but rather a clarification so our profession may better represent itself to the public, to the greater medical community, and also to our legislators.

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<sup>26</sup> “It was decided that codes describing the procedure of needling with no needle retention are to be created. The placement for these codes will be under the code set for trigger point injections. (This resides in the medical-surgical section of the code set, and not under either acupuncture nor physical medicine and rehabilitation.) Accepted addition of codes 205X1, 205X2 to describe needle insertion(s) without injection(s). Codes will become active January 1, 2020. Copyright 2018, American Medical Association, All rights reserved. CPT is a registered trademark of the American Medical Association. Updated October 30, 2018.” Report from the American Medical Association CPT Code Committee meeting September 27-29, 2018. Boston, MA. Retrieved on July 28, 2019, from [http://www.asacu.org/wp-content/uploads/2018/10/ASA-CPT-Code-Meeting-Update-October-2018\\_final-10\\_30\\_18.pdf](http://www.asacu.org/wp-content/uploads/2018/10/ASA-CPT-Code-Meeting-Update-October-2018_final-10_30_18.pdf)

<sup>27</sup> CPT® Editorial Summary of Panel Actions February 2019. Retrieved on July 28, 2019 from [https://www.ama-assn.org/system/files/2019-03/february-2019-summary-panel-actions\\_0.pdf](https://www.ama-assn.org/system/files/2019-03/february-2019-summary-panel-actions_0.pdf)

## Applicant Group Presentation - Presenter #2

Testimonial for Sunrise Review August 2, 2019

Carly Samish, LAc, LMT

Board of Directors, Washington Acupuncture and Eastern Medicine Association

Contact: c.samish@weama.info

My name is Carly Samish, I am an acupuncturist with training in Japanese style acupuncture. I work with hospice patients and in private practice. I am also a massage therapist and an instructor at East West College of the Healing Arts in Portland.

As part of our clarification of scope of practice I will be presenting about the use of non-inserting needles.

Acupuncture as a system of medicine involves stimulation of the acupuncture points, which can be accomplished by contacting the skin with non-inserting tools,

Non-inserting needles provide the benefits of acupuncture and are often more appropriate for children, or sensitive or medically fragile individuals.

The use of non-inserting needles dates back to the earliest records of acupuncture, in the Chinese classical text the Huang Di Nei Jing Ling Shu where 9 types of medicinal needles are described, with only one being an inserting needle, the filiform needle.

When Chinese medicine made its way to Japan, the Japanese acupuncturists developed and evolved the use of the non-inserting needles; while in China the medicine developed around the use of the filiform needle.

Traditional Japanese style acupuncture is still practiced and taught in acupuncture colleges in Japan and the United States, particularly in the schools of Toyohari, Meridian Therapy, and Shonishin.

Japanese style non-inserting needling techniques are very gentle, using light pressure, stroking, tapping, and holding, and are never meant to break the skin.

Shoni-shin is used in pediatric care, where gentle yet effective procedures are preferable.

In my work in hospice I often treat patients that are very medically fragile, and benefit from minimally invasive procedures. I often use the teishin non-inserting needle to hold acupuncture points or stroke acupuncture channels to calm anxiety, relieve pain, and reduce nausea.

In the Clean Needle Technique Manual, from the Council of Colleges of Acupuncture and Oriental Medicine, which is the accreditation body for acupuncture colleges, it states under the heading *Shonishin Pediatric Japanese Acupuncture Tools: A Review of the Literature*:

*“There is no evidence in the English language medical databases that there are any Adverse Effects associated with Shonishin treatments.*

[ ]

*There are no common AEs associated with the use of Shonishin products. General clean techniques, proper disinfection of such devices as noncritical devices, and vigilance to avoid use of the any reusable medical device where there is an active skin infection or trauma should be sufficient to maintain the safety record of these treatments.”*

As acupuncturists, we consider this part of our current scope of practice, part of our training, and part of the broader aspects of Eastern medicine.

This is just a clarification of our scope of practice, and to demonstrate that acupuncture is a system of medicine, and it's not exclusively about the filiform needle.

### **Applicant Group Presentation - Presenter #3**

Charis Wolf EAMP, Dipl Ac, MSTCM, PhD student  
President of WAEMA  
Representative to the American Society of Acupuncturists  
Public Education Committee of the American Society of Acupuncturists  
Practicing for 15 years in Washington state and California

This is a clarification of existing scope regarding ear acupuncture;

Auricular acupuncture, or ear acupuncture has a long history of use in China and is mentioned in one of the classic texts of Chinese Medicine; The Yellow Emperor's guide to Internal Medicine from 500 BC. The ear was later defined as a "microsystem" in that the body can be mapped in the ear. (Foot reflexology is a similar example of this).

Ear acupuncture is an ever-evolving technique and was initially based on the principles of Chinese Medicine. It emphasizes a holistic approach to medicine and treats the whole person with the stimulation of corresponding points on the ear. It is currently used as an adjunct treatment for many conditions such as addiction, mood disorders, and pain.

A recent evolution is referred to as Battlefield acupuncture by Dr Richard Niemtzow. This technique uses semi – permanent needles that are like tiny tacks that go in corresponding points in the ear for pain and calming the nervous system. The needles stay in for a few days and continue to provide some relief. The term Battlefield acupuncture (BFA) was aptly given because it is a treatment for pain that can be quickly done while in battle, when drugs and narcotics are not appropriate. BFA is a therapy known to be a form auriculotherapy and a part of acupuncture, based on the same principles.

Another relatively recent evolution of auricular therapy is known as the Nogier system developed in 1957. Dr. Nogier developed a somatopic map of the ear where the points were mapped out as a microsystem for the first time. Nogier went on to discover the Vascular Autonomic Aignal (VAS) – a distinct change in amplitude in the pulse when the ear is stimulated.

In 1980 a double blind research study was done to verify the scientific accuracy of the auricular diagnosis. There was a 75% accuracy of correct diagnosis where the patient had pain in 40 patients. Specific areas on the ear of tenderness and increased electrical conductance were noted and mapped to the corresponding location of the person's body.

This led to following studies focused on auricular acupuncture for addicts withdrawing from narcotic drugs, alcohol and nicotine which then led to the formation of NADA; the National Acupuncture Detoxification Association. This protocol is an important part of an acupuncture treatment when addressing substance abuse, as you will soon hear testimony.

Ear acupuncture techniques are taught in schools of Acupuncture and Eastern medicine and are an important part of our practice. Including it in our scope is merely a clarification, to make sure the public and legislators know that we have this knowledge and are able and willing to incorporate these effective and evidence based treatments for the people in our state.

Language for Auricular Acupuncture:

(c) All points and protocols for ear acupuncture including, but not limited to, auricular acupuncture, national acupuncture detoxification association protocol, battlefield acupuncture, and the Nogier system;

To whom it may concern!

My name is Barbara Paul-Mayer. I have been a licensed Acupuncturist in Washington State since 1993. Besides working in private practice, I have also been working at Didgwalic, a Methadone Clinic in Anacortes, Washington. Didgwalic sees about 250 patients per day with another 200 people on the waiting list. It recently received the National Indian Health Services Directors Award for 2018. Didgwalic is considered to be the only treatment center in the country that provides Narcan, drug counseling, medical attention, medical assisted drug treatment, mental health counseling, and Acupuncture, all under one roof. It even provides transportation and clothing.

The reasons that Acupuncture was chosen as one of the modalities at Didgwalic is:

- 1) Acupuncture has been shown to help with cravings for:  
Smoking  
Alcohol  
Drugs  
Opioids
- 2) Acupuncture has been shown to help with :  
Stress  
Anxiety  
Depression  
Insomnia
- 3) Acupuncture has been shown to help with: Pain Management
- 4) Acupuncture has been shown to help with : Side effects of coming off drugs,  
Withdrawal symptoms

5) Acupuncture is inexpensive and can easily be administered in group settings, thus allowing no visit limitations.

Many times people with substance abuse disorders get there because of drugs given to them by their providers for pain management. Which can eventually turn into chemical dependency and heroin use (because it is cheaper and easier to get than drugs). The aim here is to relieve pain with acupuncture so the pain drugs are not necessary, or non-opioids such as Ibuprofen and Tylenol are enough help. I would say that a good 40 percent of the patients I see at Didgwalic are in that category. Often the patient had health issues as a child and has been given prescription pain relievers for a long time.

Here are some testimonies from my patients at Didgwalic: (fictitious names)

Testimony:

“My name is LeeAnne. I am a heroin addict, I go to acupuncture 1-2 times a week and have been going for 8 months. Acupuncture has helped my cravings for drugs and alcohol and it helps my stress. I have been clean for 10 months. This is the longest time I have been clean. I strongly believe the acupuncture has helped.”

**Testimony:**

My name is Rick. I have been an active IV heroin user for 18 years. Due to several massive injuries to my legs, arm and chest, the first one when I was 14 years old, I was in severe and chronic pain. I was given prescription opioids from then on. I became a client at Didgwalic in November of 2018 and started with Acupuncture right away and after several regular sessions I was able to stop using heroin even before I was at a stable dose of methadone. I have also not been this pain free since before my injuries. I could not imagine what my recovery would look like today without this service. This has been the only time that I have been able to put any kind of clean time together, (9 months) and not be overwhelmed with cravings and urges to use.

Treating substance abuse has been in our scope of practice for a long time. Acupuncture is an accepted treatment worldwide for various clinical conditions, and the effects of acupuncture on Opiate addiction have been investigated in many clinical trials. The present review systematically analyzed data from randomized clinical trials published in Chinese and English since 1970. We found that the majority agree on the efficacy of acupuncture as a strategy for the treatment of opiate addiction. (Evidence Based Complementary and Alternative Medicine, Volume 2012, Article ID 739045, "Acupuncture for the Treatment of Opiate Addiction").

Thank you for your time.

Barbara Paul-Mayer AEMP, MAc  
360 336 6809 office / 360 829 2053 cell  
skagitwholehealth@frontier.com  
8/2/2019

## Adding Epinephrine, Oxygen and Local anesthetics to the Acupuncture and East Asian Medicine Scope of Practice

My name is Susan Shultz. I am a dual licensed Chiropractor and Acupuncture and Eastern Medicine Practitioner. I have been practicing Point Injection Therapy since 1994 in Vancouver WA. All of the speakers before me have talked about the Clarification of our existing scope and now I will speak to the expansion of our scope.

Today I will explain why the addition of Epinephrine, Oxygen and Local anesthetics to our scope is important. I would like to note that Point Injection Therapy which has been in our scope since 1985 with not one safety issue.

The use of Epinephrine is currently taught in the 24 hours of Point injection Therapy Training required by the Department of Health

Our current statute does not provide the authority to use epinephrine for PIT, but it is allowed under RCW 70.54.440 that was created to allow an authorized entity to gain access to an "Epinephrine auto-injector" through an authorized prescriber: The problem for EAMPs is that you need to get a prescription to purchase the EpiPen for your office, which makes it close to impossible for us to carry it and use it even though we are trained to do so.

I called (3) pharmacies in the Vancouver area to see how much an auto-injector costs. Fred Meyer, Walgreens and Walmart.

At Fred Meyer

Generic auto-injector = \$693.00.

Brand Name EpiPen = \$730.00.

At Walgreens

Generic auto-injector - \$375.99

Brand Name EpiPen - \$739.09

At Walmart

Generic auto-injector - \$360.25

Brand Name EpiPen - \$683.47

The Generic Auto-Injector price ranges from \$360 - \$693

The brand name EpiPen price ranges from \$683 - \$730

And – you are suppose to have 2 of these - so on the low end, the price would be \$720. The shelf life is 20 months

On top of needing a prescription for the EpiPen, the cost is prohibitive. In contrast, through a pharmaceutical supply house, a preloaded 1cc syringe of epinephrine costs a mere \$5.95. If I have (2) of them in office that is less than \$12. Being able to purchase this pre-loaded syringe would save 100's of dollars for the practitioner as well as the patients. The exorbitant cost is a barrier to provide best care for the public, epinephrine should be added to our RCW.

We already have training requirements in law for using EpiPens. The purpose of our new scope increase to add epinephrine is to be able to purchase small amounts of epinephrine in a pre-loaded syringe that is much less expensive for the practitioner who wants to keep epinephrine in their office, but it is not our intent to make it a requirement. Currently it is not a requirement in WA. No state that allows PIT requires epinephrine in office.

Adding epinephrine to our scope will create the pathway for purchasing the epinephrine without requiring an authorized healthcare provider to write a prescription for it. This would facilitate the process for the practitioners, raise the level of safety precautions for point injection therapy while also lowering the cost to practitioners as well as patients (because the cost would cascade down to the patients for the service)

## RE ADDING OXYGEN TO OUR SCOPE

Emergency oxygen is delivered from a medical oxygen cylinder via an oxygen mask.

The management of anaphylaxis and the associated emergency protocol can be taught during the safety portion of the 24 hours of training currently required before performing PIT. There is ample time within the 2 hours safety training requirement to teach the safe use of epinephrine and emergency oxygen in a clinical setting.

The problem for AEMP's is that in order to purchase medical oxygen, you need a prescription. This is the same problem we have with getting epinephrine. This is an unnecessary hardship on the practitioners who would like to have this higher level of precautionary measure in case of adverse reactions. Oxygen should be added to our RCW for patient safety and ease of practice for those of us who want to keep oxygen in our clinics.

The purpose of our new scope increase of adding oxygen will create the pathway to purchase a medical oxygen tank, regulator and oxygen mask without requiring an authorized health care provider to write a prescription for it. It is not our intent to make it a requirement. All 3 western states that allow PIT have oxygen written in to their statute, No state that allows PIT requires oxygen in office.

## RE adding LOCAL ANESTHETICS to our scope

Local anesthetics are widely recognized as agents used in point injection therapy both in Eastern Medicine and allopathic medicine. Local anesthetics are consistent with Best Practice, are used for the comfort of the patient and are easily metabolized. Local anesthetics are non-narcotic and non-habit forming and local anesthetics are not listed in schedules I through V. Local anesthetics are an essential component in the majority of solutions used in 'Best Practice' Point Injection Therapy performed by physicians, nurse practitioners and physician assistants. Without local anesthetics as part of the allowable injectables in our scope, patients seeking the relief provided by point injection therapy will have reduced options when seeking care from Acupuncture and Eastern Medicine Practitioners than when seeking care from these other providers.

All 3 western states (Colorado, Utah and New Mexico) who allow Point Injection therapy specifically list local anesthetics in their list of injectable substances.

I have submitted (2) letters from WA Acupuncture and Eastern Medicine Practitioners who use PIT and (5) letters from instructors of PIT plus a letter from Dr William Fassett, who has taught pharmacy law and ethics at the University of WA, all these professionals recommend the addition of local anesthetics to our scope. Dr. Fassett specifically addresses the safety aspects in use of local anesthetics.

Adding Epinephrine, Oxygen and Local Anesthetics to our scope is cost effective, provides consistency of treatment amongst all practitioners who provide Point Injection Therapy and they provide safety and comfort for our patients

Thank you for your time, I'd be pleased to answer any questions.

Susan K. Shultz, DC, AEMP

## Panel follow up to applicant presentation

Following presentation of the applicant report/proposal, a hearing panel asked clarifying questions of the applicant group.

The themes of the questions and applicant group responses were:

- Where on the body is point injection therapy performed, near the head and neck, and are there additional risks?

Response was that it is performed on muscles and trigger points and are performed everywhere acupuncture is performed. Some injections are to the face and neck, for instance for facelifts.

There is a risk of allergic reaction to substances being injected. The applicant group hasn't heard of an adverse reaction.

- What is the emergency protocol, call 911 and then treat?

The response was that an acupuncturist is taught in point injection therapy training to call 911 and administer epinephrine and oxygen to stabilize the patient until emergency help arrives.

- Can you provide examples of patient confusion regarding dry needling?

The applicant group gave examples of a dry needle company in Kirkland that markets what they call dry needles to physical therapists in Washington even though it's not legal. Another story was provided of a patient who received dry needling from a physical therapist in Colorado and then asked his acupuncturist here if she was able to perform dry needling as an acupuncturist.

- Can you clarify the issue with CPT codes? Are you clarifying the scope for billing purposes?

The response was that it's not for billing purposes since the CPT code is already in the scope of practice of acupuncture.

- What are the Washington State Medical Association's (WSMA) concerns about local anesthetics?

The response was that they requested clarifications on when local anesthetics would be used. They said some of it can be worked out in rule to provide specifics instead of it being for broad use. The intent is for it to be used during trigger point work and is the

majority of where this would be used for patient comfort. They stated they will work with WSMA on addressing their concerns and using best practices.

- Don't you worry that listing specific modalities and diagnoses may limit your scope?

The response was that they are trying to figure out how to explain ancient practices into Western terminology. Physical therapists state since they are using western terminology, acupuncturists don't do it. Acupuncturists are still trying to state what acupuncture is in terms patients will understand. There is a lack of mutual understanding of acupuncture practice so they want to ensure these techniques apply without listing every technique they do.

- Why do you need to add treatment substance use disorders when that's a diagnosis?

The response was that there are reimbursement and awareness issues with Medicare and Medicaid for acupuncturists performing treatment.

- Why the need for the clarifications (in general)

The responses were that the scope doesn't fully reflect how acupuncture is practiced in the west and they are trying to capture more details of what they do. Physical therapy comments show they believe acupuncturists don't perform dry needling and that it's a physical therapy procedure. We want to ensure it's clear we also do it.

Patients may not read our regulations but other practitioners might. They don't understand our training and what we do. This would show them we are doing these procedures and are trained to do them.

The applicant group also provided follow up after the hearing to include their requirement to notify patients what is in their scope of practice, in RCW 18.06.130 and WAC 246-803-300 (follow up comments are at the end of this hearing summary).

## **Public Testimony**

Six physical therapists signed in or testified in opposition to the proposal and two signed in with concerns. Reasons for their opposition included:

- Adding dry needling to the acupuncture definition is anticompetitive, appearing to give acupuncturists the sole rights to perform these procedures.
- The 2016 sunrise review that proposed adding dry needling to the physical therapy scope of practice stated that it fit within the physical therapy scope if adequate education and training were included in the law.
- Adding intramuscular needling and dry needling to the points stimulated by acupuncture needles doesn't make sense because these are practices not "points."
- Adding dry needling is a violation of antitrust law.

- There is no evidence of patient confusion regarding acupuncture and dry needling in states where physical therapists are authorized to perform the procedure (citing a Florida State Oriental Medicine Association vs. department of health case where the administrative court found no evidence of patient confusion).
- It's clear that acupuncture and Eastern medicine are based in traditional Chinese medicine, whereas physical therapy is based on movement science based in Western medicine.
- The dry needling proposal will harm the public by blocking access to the procedure by other licensed health care providers. They cited a North Carolina lawsuit against the physical therapy board that ended up in the state Supreme Court which ruled dry needling was part of the practice of physical therapy in that state.

**Panel follow up:**

The panel asked questions about whether physical therapists believe the acupuncture statute can restrict the practice by other professions, stating they can't do that.

The response was that it could take litigation like North Carolina to fight other professions trying to own a modality. They stated fundamental agreement that it can't be done in the acupuncture law but stated they want to avoid litigation to prove it.

They also stated they don't believe acupuncture and dry needling are identical and cite the 2016 dry needling sunrise that found that acupuncture and dry needling are distinct techniques. They include arguments for why dry needling is not acupuncture and why it shouldn't be included in the scope clarification. (These are not relevant to this sunrise review and so aren't listed in detail).

**Acupuncturists**

In addition to the five members of the applicant group, eight acupuncturists signed in or testified in support of the proposal for the following reasons:

- The scope of practice needs to be clarified so that it includes noninsertion tools because acupuncture is currently defined as insertion of a needle. This leaves out things like Japanese acupuncture, which does not include insertion of a needle, which also raises concerns insurance may not cover this procedure.
- Acupuncturists want to ensure adequate training for dry needling but not restrict others from practicing it within their legal scope of practice.
- Epinephrine should be added because it's very cost effective to get it in syringes as compared to an epinephrine autoinjector.
- The other substances are very effective in point injection therapy. There is a very low risk of an adverse reaction but an acupuncturist may be committing malpractice if they don't have them ready to use for an emergency.

- There is a large communication gap around acupuncture practice and the scope of practice has been vague. Other professions are trying to co-opt this practice by calling it something else so this needs to be addressed in statute.
- Some history was provided on the use of hypodermic needles in the past and how the practice has involved.
- The CMS CPT Code Committee equates dry needling to trigger point acupuncture so it's invalid to say they don't share a specific therapeutic needling technique to treat musculoskeletal conditions. It's the same CPT code.
- Acupuncture isn't covered by Medicaid for substance use disorder treatment.
- Auricular acupuncture is very effective for treating PTSD in refugees and veterans.

**Panel follow up:**

The panel asked follow up questions of those testifying about:

- Why acupuncturists can't use the term dry needling already without a change to the statute.
- If ashi points are already in the definition of acupuncture, why does it need to be added, especially if acupuncturists believe the term is being used incorrectly and is redundant.
- How another profession adding dry needling to their scope would prevent acupuncturists from performing it?

The responses were that some acupuncturists already use the term "dry needling" because they have to educate patients on what they do and on their level of their education and need to use terms patients and other types of providers understand. Also, other providers don't understand the work of acupuncture and try to define what acupuncture is without understanding it.

They added that they want to clarify their scope of practice in statute for legislators as well who don't understand what is in their scope of practice, and that this is a preventative measure to ensure physical therapists don't say dry needling is physical therapy, not acupuncture.

It was added that these clarifications have all become high profile due to insurance reimbursement and substance use disorder treatment due to the opioid crisis. Acupuncturists want to ensure it's clear they can provide substance use disorder treatments. They also want to ensure if physical therapists pass a bill for dry needling that it wouldn't preclude acupuncturists from performing it.

**Other Professions**

The Washington Association of Naturopathic Physicians (WANP) discussed the scope of practice issue with "including, but not limited to..." which appears to expand the scope. They stated it

leaves it open and broad and could cause confusion. They requested the acupuncturists ensure it's it remains tied to Asian medicine. They also stated that injection of substances needs to be clearly limited to point injection therapy. They supports oxygen and epinephrine for emergency purposes but request it's clear oxygen is limited to emergency purposes since there are other uses for it. They added that acupuncturists need to include continuing education.

The Washington State Medical Association (WSMA) stated they encourage inclusion of acupuncturists in treating pain. They listed some concerns regarding some of the terms and have brought them to the attention of WAEMA who agreed to work with WSMA.

Concerns with diagnosing and treating disease outside Eastern medicine – the definition change doesn't include this context – need to amend the draft language to add this context back in. "including, but not limited to" is too broad.

Not opposed to local anesthetics being added but need to ensure they can't be used for their own value but are within point injection therapy.

## Follow Up From August 2 Public Hearing

### From Applicant Group:

Please include this response as part of the commentary for the AEM sunrise review:

This commentary is to specifically address why the scope clarification involving dry needling is needed for Acupuncturists and Eastern Medicine practitioners;

The criteria for the sunrise review states that once a need to regulate a profession has been identified, “the regulation adopted by the state should be set at the least restrictive level consistent with the public interest to be protected.”

In section 2 it goes on to state that regulation shall be imposed “for the exclusive purpose of protecting public interest.” Subsection (b) then goes on to specify “The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability.”

The clarification of scope to include Dry Needling, and IMS techniques is to assure that the public, other medical professionals, legislators and insurance companies are all aware that our profession offers these services.

Due to the language around these techniques being newly defined in Western medical terminology, and our medicine being based on principles of Acupuncture and Eastern medicine, there has been a lack of clarity around the technique being in our scope as well as a lack of awareness in the medical professional world. As a consequence of integrated medicine, there is new emerging language in Western medical terminology to describe aspects of Acupuncture and Eastern Medicine. As our current RCW is written, it does not take this new development into consideration and this is misleading and inaccurate. Our academic training incorporates the principles of Western medicine along with Acupuncture and Eastern medicine.<sup>1</sup>

By including the terminology in our scope and clearly spelling out that it is within the scope acupuncture, we are declaring that modern descriptions of our practice are also within our scope. The addition of language referring to modern therapeutic treatments also addresses this same concern.

Under the Applicants for regulation – Information section; RCW 18.120.030

(1) A definition of the problem and why regulation is necessary;

(b) The extent to which consumers need and will benefit from a method of regulation identifying competent practitioners, indicating typical employers, if any, of practitioners in the health profession;

(4) The benefit to the public if regulation is granted:

(b) Whether the public can identify qualified practitioners;

<sup>1</sup> (1/3 of our training is Western science) [https://bastyr.edu/sites/default/files/2019-20%20MSA-MSAOM\\_1.pdf](https://bastyr.edu/sites/default/files/2019-20%20MSA-MSAOM_1.pdf)

(c) The extent to which the public can be confident that qualified practitioners are competent

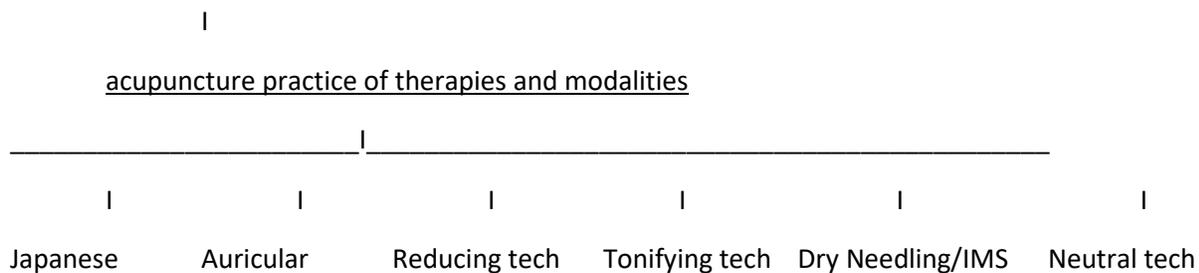
(d) Assurance of the public that practitioners have maintained their competence

When looking for information on Dry Needling, there is ample amounts of information from Chiropractors, PT's, and even MD's. Many Dry Needling classes won't accept acupuncturists to take their classes, while they will accept other medical professionals that have no previous experience working with needles therapeutically. There are companies that sell Dry Needles, which are acupuncture needles but marketed as Dry Needles specific to the technique with information specific to PT's.<sup>2</sup> This is misleading to the public as well as other health professionals. Patients and other healthcare professions should be aware that this service is readily available to the public from Acupuncturists and Eastern medicine practitioners, and we should be allowed to take the Dry Needling classes from other professionals as well.

Another example of lack of clarity around who does Dry Needling was a patient of mine that came from the UW pain clinic after receiving a treatment from a Doctor there. This technique is within the scope of MD's, but she was not aware that it is a part of the practice of acupuncture that MD's do. In the patient medical record from the pain clinic, it referred to this technique as Trigger Point needling – so we must also be clear that this terminology is included.

Acupuncture is an overarching term for a system of medicine that is based in Acupuncture and Eastern medical (AEM) theory. This involves medical theories as well as practices and techniques that are all based on the principles of AEM medicine. The techniques of acupuncture; which involve therapeutic insertion and non-insertion techniques also have quite a few modalities that are considered within the definition of acupuncture:

Acupuncture and Eastern medicine:



This is a partial list of needle-based therapies that are included within the practice of acupuncture. Of these therapeutic techniques Dry Needling / Intramuscular stimulation/ Trigger Point and Motor Point stimulation are the only ones that are currently described more commonly in Western medical terminology (the Eastern terminology relates to ashi points, hua tou jia ji points; using “bringing fire to the mountain” technique.) Because of this difference in language there is a lot of confusion. For further explanation of this please see the following paper: <http://www.asacu.org/wp-content/uploads/2019/03/Dry-Needling-is-Acupuncture-McIntyre-A.pdf>

<sup>2</sup> <https://chpgc200ekf7j5hr.mojostratus.io/channels/post/four-reasons-dry-needling-is-about-to-explode>

Several claims have been made that Dry Needling is not acupuncture which furthers the confusion. In just considering the statements submitted to the DOH from physical therapists:

- Please refer to the testimony of Susanne Michaud where she states that acupuncture and dry needling are distinct techniques and that she would never send a patient to an acupuncturist for dry needling, but she will send them to ND's and physiatrists.
- The testimony of Paul Killoren PT, also states that dry needling is unique from acupuncture.
- Comments from David Bond states that he questions whether our scope "should include the techniques or terms "intramuscular needling" or "dry needling" in their scope of practice at all. These are terms from techniques from western medicine and physical therapy" and goes on to say that in his professional opinion these are different from acupuncture.

In the statement from PTWA, they declare that the practice of Acupuncture is different from Physical Therapy – which is true. But both of our medical professions perform some similar techniques and modalities and we also use the same billing codes when we do so. There is an overlap between the professions even while we practice from different diagnostic principles. We both do manual therapy for example-

And again we see a statement "that dry needling and intramuscular needling are different from acupuncture."

This failure of medical professionals to accept that Dry Needling is a technique currently practiced by Acupuncture and Eastern Medicine Practitioners and taught in our schools is a misunderstanding that requires clarity. Just as there is overlap for manual therapy, there is an overlap for dry needling and intramuscular stimulation.

We are in agreement with physical therapists that this technique is very useful, we see the benefits literally every day. With the opioid epidemic, which is really a pain epidemic, these treatments are beneficial for a large number of people. It is important that medical professionals, insurance companies and the public all have clarity about what this treatment is, who can benefit from it and most importantly where they can go to get it.

This is the reason for the scope clarification - in accordance with the requirements for the Sunrise Review; the public should be able to easily be able to identify qualified practitioners that have the correct levels of training and education to perform this technique in Washington state. Furthermore, this would clarify that we as Acupuncturists and Eastern medicine practitioners are qualified and competent practitioners of this technique to other medical professionals as well as Health Insurance providers.

This may be even more important when the CPT codes that correspond to the needling technique come out in 2020. These codes refer to Dry Needling and Trigger point needling, further specifying that the technique is non-retention, non-injection needling. With the growing awareness of this technique much research is being done by other (than AEMPs) healthcare professionals to consider all of the benefits, and there are many. Many studies with positive results are focused on headaches<sup>3</sup>, which is a diagnosis code that recently got removed for Acupuncturists under Regence. If insurance companies aren't aware

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486992/>

that we are doing this technique, they could further deny us payment for this and patients wouldn't be able to choose an AEMP for their full breadth of scope.

As we move forward into the healthcare system and integrated care, it is important for us as practitioners to show clearly what our scope of practice is so that medical providers better understand our scope and patients will have the most options and opportunities to get the care they need by well qualified practitioners.

A clarification of the case in Florida; the courts there decided that Dry Needling was clearly not within the scope of PT's because the procedure of a needle piercing the skin was not within the scope of physical therapists in the state of Florida. <sup>4</sup>

A clarification of the case in North Carolina: there it was determined that Dry Needling was within the scope of physical therapists. The anti-trust case was not about the use of the terminology, but the attempt of acupuncturists to stop physical therapists from practicing through the dissemination of cease and desist letters.<sup>5</sup> (To be clear: we have no intention of limiting the practice of others and are merely trying to clarify our scope)

Thank you for your consideration of this matter. We hope to come to better mutual understanding of each other's professions in order to work better together through these clarifications.

Charis Wolf LAc, AEMP  
Dipl Ac, MSTCM, PhD-s  
President, WAEMA  
Representative to the American Society of Acupuncturists  
Public Education Committee, American Society of Acupuncturists

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I wanted to provide the WAC reference associated with our statement regarding the requirement to inform the patient of the AEMP scope of practice:

**WAC 246-803-300**

**Patient notification of qualifications and scope of practice.**

East Asian medicine practitioners in the state of Washington must provide to each patient prior to or at the time of the initial patient visit the qualifications and scope of practice form. The form must include:

- (1) The East Asian medicine practitioner's education. The degree obtained or if the education was by apprenticeship, the dates and locations of the didactic and clinical training.
- (2) License information, including state license number and date of licensure.
- (3) A statement that the practice of East Asian medicine in the state of Washington includes the following:

<sup>4</sup> [https://www.news4jax.com/health/judge-pokes-hole-in-dry-needling-rule?\\_\\_vfz=medium%3Dsharebar&fbclid=IwAR07Z\\_wfPNQJQIcTrugzmWTHJ-j98keG4v-OfMVHetCltMUNuwj\\_ju1RqaA](https://www.news4jax.com/health/judge-pokes-hole-in-dry-needling-rule?__vfz=medium%3Dsharebar&fbclid=IwAR07Z_wfPNQJQIcTrugzmWTHJ-j98keG4v-OfMVHetCltMUNuwj_ju1RqaA)

<sup>5</sup> <https://www.law360.com/articles/886552>

- (a) Acupuncture, including the use of acupuncture needles or lancets to directly and indirectly stimulate acupuncture points and meridians;
- (b) Use of electrical, mechanical, or magnetic devices to stimulate acupuncture points and meridians;
- (c) Moxibustion;
- (d) Acupressure;
- (e) Cupping;
- (f) Dermal friction technique;
- (g) Infrared;
- (h) Sonopuncture;
- (i) Laserpuncture;
- (j) Point injection therapy (aquapuncture);
- (k) Dietary advice and health education based on East Asian medical theory, including the recommendation and sale of herbs, vitamins, minerals, and dietary and nutritional supplements;
- (l) Breathing, relaxation, and East Asian exercise techniques;
- (m) Qi gong;
- (n) East Asian massage and Tui na (which is a method of East Asian bodywork); and
- (o) Superficial heat and cold therapies.

(4) A statement that side effects of the treatments listed above may include, but are not limited to, the following:

- (a) Pain following treatment;
- (b) Minor bruising;
- (c) Infection;
- (d) Needle sickness; and
- (e) Broken needle.

(5) A statement that patients must inform the East Asian medicine practitioner if they have a severe bleeding disorder or pacemaker prior to any treatment.

[Statutory Authority: Chapter [18.06](#) RCW and 2010 c 286. WSR 11-17-105, § 246-803-300, filed 8/22/11, effective 9/22/11.]

And here is the RCW. It appears that acupuncturists are the only profession that is required to present their scope of practice to a new patient. According to Vicki Brown this dates back to 1985 when acupuncturist first gained licensure.

### **RCW [18.06.130](#)**

#### **Patient information form—Penalty.**

\*\*\* CHANGE IN 2019 \*\*\* (SEE 1865-S.SL) \*\*\*

(1) The secretary shall develop a form to be used by a person licensed under this chapter to inform the patient of the scope of practice and qualifications of an East Asian medicine practitioner. All license holders shall bring the form to the attention of the patients in whatever manner the secretary, by rule, provides.

(2) A person violating this section is guilty of a misdemeanor.

Attached are the comments from WAEMA in response to all the feedback we got. Please let us know if you have any further questions-

The Washington Acupuncture and Eastern Medicine Association (WAEMA) would like to respond to additional comments made at the Acupuncture and Eastern Medicine Sunrise Review Hearing on August 2, 2019.

We would like to start with why a clarification of scope falls under a Sunrise Review Criteria. State laws require that Acupuncture and Eastern Medicine Practitioners (AEMPs) provide a copy of their scope of practice at the time a person first becomes a patient. Here is an example that the department has suggested practitioner use when initiating treatment with a patient: Patient Notification of Qualifications and Scope of Practice Sample Form (PDF)

In response to Katie Wolt's statement at the hearing that "patients don't know or care what is in the Acupuncture Scope of Practice and that perhaps education is needed instead of a clarification in state law." We strongly disagree that a patient does not know or care what is in the AEMPs scope of practice. The patient notification form is where the education of a patient receiving acupuncture begins. A patient should be educated when they review the scope of practice to reduce confusion that acupuncturists treat substance abuse disorder, that they use Japanese "non-insertion" needles for patients who may be medically fragile or do not tolerate needles well, that trigger points, dry needling and intramuscular stimulation are all part of the scope of practice of AEMPs and that is why it is needed in statute.

In response to Jeb Shepard, WA State Medical Association comments and Bob May, WA Naturopathic Physicians:

Both associations expressed concerns regarding the term "including, but not limited to" as too broad. WAEMA has suggested alternative language to both associations to review that would be more specific in the bill draft. WSMA also requested that the language related to "treat and diagnose" mirror the language in RCW 18.06 (SHB 1865) and we will be revising our bill draft to reflect the highlighted changes below:

(1) "Acupuncture" or "Eastern medicine" means a ((health care service utilizing acupuncture or Eastern medicine diagnosis and treatment to promote health and treat organic or functional disorders and includes the following)) holistic system of medicine often referred to as traditional Chinese medicine, Eastern medicine, and by other terms, which includes a variety of traditional and modern therapeutic treatments including, but not limited to, such as, the practice of acupuncture techniques and herbal medicine to maintain and promote wellness, prevent, manage, and reduce pain, treat substance use disorder, and diagnose and treat disease to promote health and treat organic or functional disorders.

Both associations expressed concerns with the injection of "local anesthetics, oxygen and epinephrine" and requested additional clarification. We propose the following change to the bill language to address their concerns:

((l)) (m) Point injection therapy, as defined in rule by the department. Point injection therapy includes injection of substances, limited to saline, sterile water, herbs, minerals, vitamins in liquid form, ((and)) homeopathic and nutritional substances, and local anesthetics consistent with the practice of acupuncture or Eastern medicine for reduction of pain during point injection therapy injections and with training to be further defined in rule. An acupuncturist or acupuncture and Eastern medicine practitioner using point injection therapy who has met the training and education requirements established pursuant to RCW 18.06.230 may use local anesthetics, oxygen, and epinephrine for potential emergency purposes, such as an allergic or adverse reaction, for patient care and safety.

Bob Mays stated that Acupuncture and Eastern Medicine Practitioners (AEMP) are not required to complete continuing education consistent with other direct access health care providers. As of July 28, 2019, SHB 1865 Acupuncture and Eastern Medicine addresses this issue by requiring CE's, with the number of hours to be determined in rule. The intention of WAEMA is to have CE requirements consistent with the national NCCAOM requirements of 60 hour every 4 years.

In response to Susanne Michaud, PT, we are suggesting the following modifications to address their concerns about the location of "intramuscular needling and dry needling" in the bill draft language and have agreement with the PTs that this language would be acceptable:

(a) ((Acupuncture, including the)) Use of presterilized, disposable needles, such as filiform needles, and other acupuncture needles, syringes, or lancets to directly and indirectly stimulate meridians and acupuncture points ((and meridians)), including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other nonspecific points throughout the body;

(b) Use of electrical, mechanical, or magnetic devices to stimulate meridians and acupuncture points ((and meridians)), including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other nonspecific points throughout the body;

(c) Intramuscular needling and dry needling of trigger points and other nonspecific points throughout the body in accordance with Acupuncture and Eastern medicine training;

We also have concerns about her statement that AEMPs "slipped in" the term trigger point and Ashi points to recent rulemaking at DOH around their scope of practice. This was a very thorough public meeting rulemaking process that PTWA was represented at and where they opposed the language being added to a scope clarification. We strongly disagree with her contention that this language gives acupuncturists exclusive purview over dry needling and intramuscular stimulation.

Currently two bills waiting for a public hearing before the Senate and House Health Care committees, SB 5642 and HB 1260 Intramuscular Needling, would expand the scope of practice for PTs. The only limit is their ability to get the bill passed through the state legislature. Her threats of a lawsuit based on the North Carolina class action is not a precedent in this case. If the PT's are able to pass legislation that provides for adequate training and an adequate clinical component, then the association would be more amenable to supporting it in their scope of practice.

We are not opposed to continuing the dialogue with the Physical Therapy Association of Washington (PTWA) and met with them numerous times over the past few years in facilitated conversations to resolve our differences. The contention is not around whether they can or should practice dry needling

and intramuscular stimulation, it is around the number of hours for educational and clinical training for the safe practice of dry needling and intramuscular stimulation.

Washington state law allows the PTs to expand their scope of practice through legislation. All health care practitioners in the state must adhere to these state laws governing professions. Medical doctors, osteopaths and ARNPs are already performing needling with a filiform needle. Neither this proposed bill or current law restricts other professions from passing legislation to add to their scope of practice. Current law states:

RCW 18.06.045 Exemptions from chapter.

Nothing in this chapter shall be construed to prohibit or restrict:

(1) The practice by an individual credentialed under the laws of this state and performing services within such individual's authorized scope of practice;

We also suggest that RCW 18.06.045 Exemptions from chapter, applies to the comments by Fuji McPherson who owns the Acupuncture and Integrative Medicine Institute (AIMI) that teaches ARNPs "medical acupuncture". As an owner of a school that gains financial benefit from the teaching of acupuncture to advance practice nurses, he has already gained acceptance within the ARNP scope of practice to use filiform needles for the purpose of medical acupuncture.

WAEMA would like to reiterate that in our Sunrise Review Applicant Report it states: This proposal is not intended to limit other professions from gaining access to acupuncture techniques legislatively with appropriate training, it only assures that these terms will also be understood as the practice of acupuncture, not to be superseded or disallowed by alternative definitions that may arise in the future. This proposal only impacts the scope of practice for licensed acupuncturists in Washington state.

It is our understanding that the Physical Therapy Association of WA has concerns regarding a statement in the Sunrise Applicant Report underlined below:

2. Explain how the proposal addresses the problem and benefits the public (refer to RCW 18.120.030(4)). RCW 18.120.030 requires that the public and consumers clearly understand the profession and the treatments that they provide under state law. Other professions using acupuncture (filiform) needles therapeutically are practicing acupuncture under a different name causing confusion for the public. We want to assure that any use of acupuncture (filiform) needles for therapeutic purposes is considered acupuncture under the law. Public safety could be at risk with unauthorized use of acupuncture (filiform) needles, coupled with inadequate training and potentially operating outside of their scope of practice.

As stated above, it is not the intent of the association or Sunrise Review to limit the procedure of dry needling and intramuscular stimulation to only Acupuncturist and Eastern Medicine Practitioners, but to clearly include it in their scope of practice. Although it is too late to amend the Sunrise Applicant Report, the association would like to suggest broader language be included or substituted to assist in this clarification. Instead of "is considered acupuncture under the law" replace with "is considered within the scope of acupuncture under the law".

WAEMA would like to point out that there are numerous examples of why clarification around dry needling and intramuscular stimulation are needed in the “Information Summary and Recommendations Physical Therapy Dry Needling Sunrise Review December 2016”

The Sunrise Act (RCW 18.120.010) says a health care profession should be regulated or scope of practice expanded only when:

Unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

Physical Therapy Dry Needling Sunrise Review Department Analysis: “The department finds that dry needling is an invasive procedure with potential serious risks of patient injury and death” and “There are inherent risks from any practitioner puncturing the skin with acupuncture needles and the department must ensure adequate training to safely perform these procedures while avoiding rare but serious adverse events.”

Physical Therapy Dry Needling Sunrise Review First Criterion: Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public. The proposal does not meet this criterion. Physical therapists are currently a thoroughly regulated profession with substantial training in the treatment modalities under their current scope of practice that includes up to 1,500 hours of supervised clinical training. The proposal as written adds an invasive procedure with the potential for serious risks of patient injury without offering adequate protections to the public.

The definition of dry needling appears to fall under the EAMP scope of practice and EAMPs have extensive training in needling techniques and safety. However, that does not mean other providers shouldn't also use these needles if they have adequate training and statutory authority to do so. Overlaps between scopes of practice are sometimes appropriate if evidence of adequate training to protect the public is included. The department found during this review that although the proposal submitted does not meet the sunrise criteria, dry needling may fit within physical therapy treatment of myofascial pain and movement impairments with adequate training that includes a clinical component.

The public cannot be effectively protected by other means in a more cost-beneficial manner.

There have been numerous television news stories about dry needling in Washington state, most recently on King 5 News (later identified as happening in a different state), which are in the public arena that does not clarify the need for appropriate training and clinical hours. WAEMA has attempted to correct the misinformation and educate the public but does not have the resources to counter the extensive reach of a television audience in Washington state. We hope to have the ability to educate the public through clear legislation that demonstrates the extensive training and clinical experience required for inserting filiform needling into patients.

WAEMA Analysis: Clearly the unregulated practice of dry needling can harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable. Currently the terms “dry needling and intramuscular stimulation” are not specifically stated in the scope of practice for physical therapists or AEMPs. It is not clear to the public that this is a regulated practice in Washington state.

AEMPs have the clinical hours and training necessary to safely perform these procedures that include inserting a filiform acupuncture needle into patients for therapeutic purposes. For these reasons, we request that the department support our request for clarification that AEMPs clearly have the clinical hour and training necessary to perform the practice of dry needling and intramuscular stimulation.

The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability;

WAEMA wants to guarantee that the public can reasonably be expected to benefit from an assurance of initial and continuing professional ability that AEMPs have the adequate training to provide dry needling and intramuscular stimulation by clearly stating it in their statute. The concern regarding harm or endangerment to public safety from the use of dry needling or intramuscular stimulation comes from the lack of clinical hours and training. AEMPs have the appropriate training to safely provide this treatment.

Recommendations Physical Therapy Dry Needling Sunrise Review December 2016:

The department does not support the applicant's proposal as submitted to add dry needling to the physical therapy scope of practice. It does not meet the sunrise criteria for increasing a profession's scope of practice. Rationale:

- The applicant did not demonstrate that 54 hours of training is sufficient to ensure professional ability of physical therapists to perform dry needling, which is an invasive procedure with potential serious risks of patient injury. The HumRRO analysis did not address a minimum level of training or assess current training programs for adequacy.
- There is no supervised clinical experience requirement. Physical therapists have vast training, including supervised clinical experience, in anatomy and physiology. However, physical therapist training does not include use of needles in treatment.
- The applicant report states that the majority of education necessary to perform dry needling is taught in entry-level physical therapy doctoral education. However, not all physical therapists practicing in Washington have completed doctoral level training and a doctorate is not required for licensure.

In addition, there are other challenges to implementing the proposed bill, SB 6374:

- The definition of dry needling in the bill is problematic, specifically the statement "Dry needling does not include the stimulation or treatment of acupuncture points and meridians." The physical location of myofascial trigger points, muscular, and connective tissue often correspond with acupuncture points and meridians.
- Section two does not limit the dry needling endorsement to physical therapists who have received their Doctor of Physical Therapy (DPT) degree, even though the applicant report uses doctoral level training as the basis for its assessment of physical therapists' substantial training in anatomy and physiology. The current physical therapy statute and rules allow full licensure with a baccalaureate physical therapy degree, or a baccalaureate degree plus an advanced physical therapy degree or certificate.

Physical Therapy Dry Needling Sunrise Review Second Criterion: The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability. The proposal does not meet this criterion. There are adequate laws and rules in place to assure the public of physical therapists' initial and continued professional ability to practice within their current scope of practice. The proposal does not contain similar assurances.

The applicant has not provided evidence that the proposal provides assurance of initial and continuing professional ability for physical therapists to perform dry needling safely....

For these reasons we ask that the department support the clarifications and scope expansion we request to help educate our patients and the public about the training of AEMPS in Washington state and the need for additional patient safety and comfort through the addition of the new scope expansion for Point Injection Therapy.

Charis Wolfe – member of applicant group

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**From Other Stakeholders:**

Please find the attached letter from one of my patients regarding confusion over who can practice dry needling.

I want to share with you some confusion I experienced regarding who can administer dry needling. I have experienced pain/discomfort in my right hip for several months.

Initially, I was diagnosed with having bursitis. I received an injection of cortisone in my hip area. That brought some relief. I also have been going to Physical Therapy. After several PT sessions, the Physical Therapist recommended I return to the Sports Medicine doctor. During that visit with the Sports Medicine doctor, he mentioned that he could provide a technique called "dry needling" where he would insert needles into the area and then provide electric stimulation to that area. I agreed to this procedure. It was very helpful and I had immediate relief.

When I saw Jessica for my acupuncture appointment, I shared with her that the Sports Medicine doctor had done dry needling and how it resembled acupuncture, but with the electric impulse. I was not aware that this type of application is part of what can be done by acupuncture. I am glad that my acupuncture therapist educated me that this is a technique she can perform. I have had this treatment twice and have experienced elimination of the pain I had been experiencing in my hip.

Bette Hubbard

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I'd like to add my support to the recommendations put forward in the WAEMA proposal.

I've been in private practice for 30 years, and have training in traditional Chinese and Japanese styles of acupuncture, as well as point injection therapy and orthopedic acupuncture.

Jim Stegenga, L.Ac., EAMP

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**Physical Therapy Association of Washington**  
208 Rogers St NW, Olympia WA 98502-4952

360 352-7290 · telephone  
800 554-5569

360 352-7298 · facsimile  
<http://www.ptwa.org>

*A Chapter of the American Physical Therapy Association*

August 8, 2019

Katie Wolt, Policy Analyst  
Washington State Department of Health Sunrise Reviews  
P.O. Box 47850  
Olympia, WA 98504-7850  
[sunrise@doh.wa.gov](mailto:sunrise@doh.wa.gov)

Dear Ms. Wolt:

On behalf of the Physical Therapy Association of Washington (PTWA), I am submitting additional comments on the Acupuncture and Eastern Medicine Scope of Practice sunrise review. We appreciate the opportunity to submit comments after last Friday's public hearing.

As we stated in our written comments and in testimony, one of PTWA's concerns about the applicant's proposal is their contention that dry needling and intramuscular needling belong solely in the scope of practice of acupuncturists. Thus, any other health care provider who seeks to perform dry needling or intramuscular needling would be required to become a licensed acupuncturist.

PTWA has consistently asserted in written comments and public testimony during our sunrise review two years ago, legislative testimony, and during this Acupuncture and Eastern Medicine Scope of Practice sunrise review, that dry needling and intramuscular needling performed by physical therapists is different than acupuncture. Physical therapists in 35 other states are allowed to perform these modalities without holding a license as an acupuncturist.

Therefore, we want to ensure that, should the Legislature grant physical therapists the ability to perform dry needling and intramuscular needling in Washington, physical therapists can do so under their physical therapy license and not be required to seek an additional license as an acupuncturist.

The Washington Acupuncture and Eastern Medicine Association (WAEMA) has proposed an amendment to their legislative proposal that would alleviate our concern. Specifically, WAEMA has proposed removing the reference to dry needling and intramuscular needling from Section 1(1)(b) and adding a new subsection (c):

(c)Intramuscular needling and dry needling of trigger points and other nonspecific points throughout the body in accordance with Acupuncture and Eastern medicine training and principles;

PTWA supports this new proposed language, as it clarifies that intramuscular needling and dry needling will be performed within the context of Acupuncture and Eastern medicine training and it does not restrict the ability to for other health care providers to perform dry needling and intramuscular needling within the context of that provider's education and training.

This change, coupled with the following language in RCW 18.06.045, will ensure that nothing in the Acupuncture statute will inhibit other providers from practicing within their scope of practice:

Nothing in this chapter shall be construed to prohibit or restrict:

(1) The practice by an individual credentialed under the laws of this state and performing services within such individual's authorized scope of practice...

Thank you for considering PTWA's comments and for the opportunity to participate in this important sunrise review process.

Sincerely

A handwritten signature in blue ink that reads "Erik Moen". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Erik Moen, PT  
President

## **Appendix E**

### **Written Public Comments**

## 2019 Acupuncture Sunrise Review Comments

July 31, 2019

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When determining the scope of practice of WA state health care providers performing dry needling and intramuscular stimulation, it is important to recognize the practice is in itself a technique used around the world by many different professionals, with a variety of backgrounds and scholastic training. The terms have traditionally been used by western medicine practices and made popular in the United States by physicians and physical therapists. Please consider the effectiveness, affordability, and fact this technique used by many different industries of healthcare providers can safely, and quickly, help Washingtonians treat and manage pain, dysfunction, and chronic musculoskeletal disorders conservatively, with unbelievably positive outcomes.

Please do not block myself and other people that manage chronic symptoms from effective, affordable care, allowing one profession to capitalize on a treatment style and technique.

Jacqueline Berg

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I am writing to submit my comment regarding the Sunrise Review- Acupuncture and Eastern Medicine Scope of Practice.

As a healthcare provider trained out of state OR and CA and receiving my clinical Doctorate, I have seen first-hand the benefits that “intramuscular needling” and “dry needling” can provide to people in pain when performed by an expert in the musculoskeletal system, as physical therapists and physicians are.

It concerns me that this proposed expanded scope of practice will take ownership of these terms and limit the options of citizens of Washington State to receive effective, safe, conservative care from others outside of the field of Eastern Medicine.

It is by believe that these tools are effective and safe to use in the hands of skilled providers including physical therapist and physicians. Ownership of words although seem small make large changes to my personal scope of practice. Professionally, I have become an expert in the musculoskeletal system and have spent hours of rigorously studying. I believe by changing this language would take away from my ability to provide evidence based quality care and ultimately taking away from WA citizens and their ability to receive effective care.

Brielle Kadrmas, PT, DPT

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Thank you for considering written comments during this Sunrise Review process regarding expansion of Acupuncture and Eastern Medicine Scope of Practice to include “dry needling” and “intramuscular

needling”. As the licensing board, DOH committee, and members of the WA legislature are aware – there have been several efforts to expand physical therapy scope of practice to include dry needling in WA over the past several years. These attempts have been unsuccessful to this point with much resistance from acupuncture and eastern medicine practitioners, and unfortunately has put WA behind the 40+ other states who have now allowed the practice of dry needling by PTs and other clinical doctoring professions. Allowing one profession to monopolize a tool (monofilament needle) ultimately impacts the healthcare consumer the most, by limiting access to cost-effective and non-pharmaceutical therapies. **I oppose the current proposal and the applicant’s rationale to increase acupuncture scope of practice to include “dry needling” and “intramuscular needling” on both *procedural and practical* grounds.**

For brief background, I currently live in WA and have been a physical therapist for almost 10 years, graduating from Regis University with my Doctorate in Physical Therapy in 2010. Originally from CO, and with licensure in other states (which allow needling), I was trained in dry needling in 2011 and have been an educator for Kinetacore Education since 2014. Since that time, as faculty I have instructed over 100 dry needling weekend intensives and have lectured nationally on the topic.

First, procedurally I do not believe the applicant party has adequately fulfilled the proposed criteria in RCW 18.120.010. Assertions of public confusion over needling modalities contributing to public harm is unsubstantiated, not only in WA, but in other states and countries. Additionally, large scale clinical research and liability claim data from the largest healthcare insurer in the US clearly state physical therapists performing dry needling does not introduce a statistically significant increase in severe adverse event occurrence. The applicant party also fails to delineate education, training, and cost-beneficial implications for traditional acupuncture techniques versus dry needling.

Secondly, the applicant party’s attempt to adapt all needling procedures (any use of a filiform needle) as practically defined as ‘acupuncture’ is not only unprecedented and categorically false, but anti-competitive and ultimately harmful to multi-disciplinary methodological advancement and healthcare consumer access. Again, it is worth citing over 40 US states have legislatively allowed physical therapists and chiropractors the ability to adapt dry needling into their scope of practice as decidedly unique from acupuncture. In 2018, a federal anti-trust lawsuit ruling between the North Carolina Acupuncture Licensing Board (NCALB) and North Carolina Board of Physical Therapy Examiners determined that dry needling is unique from acupuncture, that it is within the scope of physical therapy practice, and acupuncture efforts to restrict this physical therapy practice violate anti-trust regulations. Furthermore, the contention that other therapeutic professions lack adequate training and knowledge to have the ability to use filiform needles is absurd considering the academic and clinical curricula for these doctoring professions (DPT, DC, MD) is extensively more than the master’s level training of the applicant group -- specifically education in anatomy, neuroanatomy, histology, physiology, standard precautions, critical inquiry, orthopedic and neuromusculoskeletal management.

*“We want to assure that any use of acupuncture (filiform) needles for therapeutic purposes is considered acupuncture under the law”*

Ultimately, it seems the intent of the Department of Health Sunrise Review process should be to advance practice scope and innovations in healthcare, it should NOT be used as a tool to restrict other professions with inherent exclusivity of a modality or tool.

Thank you for considering commentary on this topic and denying the current proposal of acupuncture and eastern medicine scope of practice expansion.

Paul Killoren PT, DPT, CSCS

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I am writing to voice my concern regarding the additions of the ownership of terms “Dry Needling” and “Intramuscular Needling” to the Acupuncture and Eastern Medicine scope of practice in our state. These terms are specific to the practice of Physical therapists around the nation in regards to successfully treating patients with intramuscular disruption and pain, and are not to mention specifically differentiated from the practice of Acupuncture and various forms of Eastern Medicine practice. I advise and hope to see that comments made about this issue are heard and understood as we as healthcare professionals look to progress the care of our patients to the most appropriate, specific and correct treatment we can provide as a whole.

Sean Locke PTA, BS, CSCS

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I am writing to submit my comment regarding the Sunrise Review- Acupuncture and Eastern Medicine Scope of Practice.

As a healthcare provider trained out of state (Utah and Texas) and receiving my clinical Doctorate, I have seen first-hand (as both the patient and provider) the benefits that “intramuscular needling” and “dry needling” can provide to people in pain when performed by an expert in the musculoskeletal system, as physical therapists and physicians are.

It concerns me that this proposed expanded scope of practice will take ownership of these terms and limit the options of citizens of Washington State to receive effective, safe, conservative care from others outside of the field of Eastern Medicine.

Nicholas Chamley PT, DPT, OCS

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I have been practicing acupuncture services (in particular auricular acupuncture) to patients a chemical dependency clinic that also dispensed Methadone and Buprenorphine. I believe that the most effective treatment is the chemical dependency clinic MAT (medication assisted treatment) for people who have dependency problems. This treatment provides medications and counselling sessions to people who have drug dependency problems. The treatment is a lengthy process, so while they are going through MAT, patients continues to suffer from physiological (eg. back pain, neck/shoulder pain, other various pain) and psychological (eg. depression, anxiety, stress). Therefore, we provide a holistic approach to support people.

I believe that acupuncture is a practice that helps people who are struggling to stay in the chemical dependency program. People who stay in the program have a greater chance of recovery. I see many clients who are satisfied with their acupuncture treatments because it helps them manage their pain without the use of medications.

Acupuncture treatment, in conjunction with MAT, plays a significant role in client's success on their long journey of recovery.

Yoji Kobayashi

I am writing in support of specifically including language in the clarification of our acupuncture scope of practice regarding the use of **contact needling** and **non-insertion tools such as *teishin*, *enshin* and *zanshin*** that are commonly used in Japanese-style acupuncture (which I practice and teach around North America). These specific needle therapy tools have existed for millenia and are described in *Ling Shu* chapter 1. (The *Ling Shu* is the name of the earliest known book on acupuncture, published around 200 BC, which explains the theory of meridians integral to the practice of acupuncture as well as acupuncture techniques, pathology and treatment for many diseases.) The word, *Zhen Jiu* which was incorrectly translated as “acupuncture”, should actually have been translated as “needle therapy and moxibustion”.

In the West, we are primarily familiar with filiform acupuncture needles (used for insertion), but in fact there are myriad types of needles that have historically been used in East Asian medicine including the *teishin* (“sesame seed ended needle”), *enshin* (“round headed needle”) and *zanshin* (arrow headed needle) which are described in the Classics for non-insertion purposes (pressing, scraping, tapping, etc.) and widely used by Japanese-acupuncture stylists. It is most commonly used in pediatrics as it is comfortable and safe to receive, as well as with sensitive patients and the elderly.

Regarding auricular acupuncture, as co-founder and team leader of Seattle Acupuncture for Veterans, a group that provides free treatment to veterans and their families, we routinely use **auricular acupuncture** (primarily the NADA protocol) for treatment of PTSD, anxiety, depression and addiction cravings. The Pentagon has embraced the employment of “Battlefield Acupuncture” which uses a specific acupuncture protocol involving the ear. (I am currently working on a research trial with the founder of Battlefield Acupuncture, Richard C. Niemtow, MD, Ph.D., MPH, Colonel (ret), USAF, MC, FS, Integrative Medicine Consultant to the USAF Surgeon General, Director, USAF Acupuncture & Integrative Med Center Joint Base Andrews, Maryland, Assistant Professor Uniformed Services University of the Health Sciences, Former President AAMA. Editor-in-Chief: Medical Acupuncture, Senior Military Editor: Journal of Alternative and Complementary Medicine. )

Research supporting the efficacy of auricular acupuncture for treatment of PTSD, chemical dependency, cravings and pain is growing, as well as the evidence base for acupuncture and East Asian medicine generally.

I am happy to respond to any questions you may have and apologize that I am unable to come to Tumwater in person on August 2 to testify.

Brenda Loew

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I would like to submit my DISPUTE comments to the: Sunrise Review - Acupuncture and Eastern Medicine Scope of Practice.

I am a licensed physical therapist with nearly 15 years practice experience, and 3.5 years practicing as a dry needling practitioner while working in Nevada. Physical Therapist in the majority of states in our country have the ability to offer these services to our populous, and Washington residents deserve the same capacity. I have personally seen the consistently positive results that integrating dry needling has contributed to the recovery of a person’s function within the overall care under a physical therapist. We (physical therapist) are appropriately trained through our formal education and post-graduate

coursework, are able to competently educate patients, and safely implement dry needling to the neuro-musculoskeletal population.

I fully support the state of Washington establishing dry needling specific educational and training requirement similar to other states in our country. These other states have made the legal decision and/or opinion that physical therapist and other non-east Asian medical practitioners/acupuncturist are fully competent, with additional post-graduate training, to offer dry needling services.

Presently I am relocating from Nevada, where I have been a dry needling practitioner, back to Washington State and hope in the near future to competently offer dry needling services (once fully legalized) to the residents of Washington State.

Warren Womack PT, DPT

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My name is Dave Bond, and I am a licensed physical therapist in Washington State. I would like to submit a comment for the sunrise review of the acupuncture and eastern medicine scope of practice in this state.

I question whether it is appropriate for acupuncturists and eastern medicine practitioners to have the techniques or terms "intramuscular needling" or "dry needling" in their scope of practice at all. These terms are for techniques from western medicine and physical therapy. In my professional opinion, intramuscular/dry needling are different than acupuncture. The framework for understanding human anatomy and physiology, indications for use of techniques involving stimulation of tissues with monofilament needles, and proposed mechanisms of action for these interventions are quite different for acupuncture compared to intramuscular or dry needling.

Beyond my objection to adding intramuscular and/or dry needling to the acupuncturist and eastern medicine practitioner scope of practice, I am resolute in asserting that this profession should **NOT** be the only one in Washington State authorized to use these interventions. It is clear that medical and osteopathic physicians have the training, expertise, and knowledge to safely use intramuscular/dry needling to treat their patients. It is also clear that physical therapists are adequately educated and use intramuscular/dry needling safely and legally in many, many jurisdictions throughout the United States. It is reasonable to presume, in due time and following due process of the legislature and/or Department of Health, that there is a possibility for intramuscular/dry needling to be codified as part of the physical therapist scope of practice in Washington State.

Pleased do **NOT** add "dry needling" or "intramuscular needling" to the practice act for acupuncturists and eastern medicine practitioners in Washington State. **MORE IMPORTANTLY**, if the sunrise review decides to include these terms and techniques in the scope of practice for acupuncturists and eastern medicine practitioners, then it should also clearly describe that other professions may also perform these techniques if they are provided for within relevant practice acts.

Thank you for considering my position on this matter. Feel free to contact me by phone or email should you have questions, concerns, or wish to discuss the matter further.

David B. Bond, PT, DPT

My name is Matthew Stuckey, I'm a licensed acupuncturist in Bellingham. I wanted to shine a light on the current work acupuncturists have been doing, in particular, for chemical dependency. In 2013, I worked at Wai`anae Coast Community Mental Health Center for their chemical dependency program on O`ahu using the auricular acupuncture protocol developed by the National Acupuncture Detoxification Association (NADA). I currently use the same acupuncture protocol for Swinomish Health Services at Didgwalic Wellness Center, which runs a Methadone program in Skagit County. At Unity Care Northwest in Bellingham, one of Bellingham's community health centers, I work with patients in chronic pain. I've been asked by the Chemical Dependency counselor and head of Behavioral Health to collaborate with their new chemical dependency Suboxone program. In all of these locations, acupuncturists like myself have been sought out to provide care by willing and eager physicians, nurses, and counselors. All over the country, both in-patient and out-patient chemical dependency clinics have been using acupuncture for decades. Patients continue to say that it helps them. We all need to employ whatever methods we can in this addiction crisis. As acupuncturists, we have a role as well.

Matthew Stuckey, Lac

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I write on behalf of Washington State Orthopedic Association where we have been made aware that there is a pending sunrise review regarding expansion of the scope of practice acupuncturist/traditional Chinese medicine providers. We would like to comment on this review and express some concerns that the proposed expansion raises for us.

We don't believe that acupuncturists are fully trained in anatomy physiology, and pharmacology. We therefore feel that the proposed expansion of scope to include injecting pharmacologic substances (local anesthetic) may put patients at risk.

We also don't believe that acupuncturist are well trained in physical examination and diagnosis nor do they have access to the broad spectrum of diagnostic tools that are used in modern medicine. Without training in and an understanding of the broad spectrum of human disease, It is very concerning that acupuncturist are requesting expanding their scope to include diagnosing and treating disease. The concern is obviously for missing important diagnoses or making erroneous diagnoses which may lead to improper or delayed treatment.

While we recognize the value of alternative therapies as part of the spectrum of care, we believe the current proposals extend the scope of "traditional Chinese medicine" into very much "non traditional" territory which could cause unintended harm to patients.

Nicholas Rajacich

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I have concerns regarding the proposed Sunrise proposal outlining the statutory criteria in chapter 18.120 RCW and proposed change to the acupuncture and eastern medicine practitioner scope of practice. The problem identified in the applicant report which is to clarify the definition of acupuncture is not needed and it appears the request is aimed specifically to exclude other health professionals from performing care that is within their scope of practice. Where the definition of and proposal tries to claim needles are only to be used by acupuncturist. I do not believe the scope of practice should be used to regulate the instruments used but rather provide a

framework for the practice itself. Therefore, the definition of acupuncture is not needed to add the substances or how the current education and training for the health profession adequately prepares practitioners to perform the new skill or service (refer to RCW 18.120.030(4)).

The current proposal cites clarifications of existing scope of practice. All of which establishes a limited criteria covered only with the completion of a master's level training provided by Washington states' approved acupuncture schools such as Bastyr University and others. The education ranges from 1,500 hours minimum to over 2,000 hours of training depending on the area of focus within the acupuncture and Eastern Medicine profession. A licensed acupuncturist must be board certified with the NCCAOM to practice in WA State

This proposal applies to changes made after 1983 and is clearly targeted to support WEAMA attempts to reverse the decision by the Nursing Care Quality Assurance Commission (NCQAC) to authorize the procedure of acupuncture into the Nurse Practitioner scope of practice based on the same criteria of training used by MD Acupuncturist established prior to 1983 to intentionally avoid conflict with the AMA while suppressing and reversing the decision by NCQAC approved in November of 2017.

The proposal regarding the nature and duration of training should be restructured to account for Medical Doctors (MD)s who already include acupuncture within their scope of practice, Nurse Practitioners (NP) and Physician Assistants (PA) who have already completed and meet the requirements for licensure in the State of Washington, and have completed an additional 300 hours of acupuncture training (which is the same criteria used for MDs) to safely perform the clinical procedure of acupuncture therapy using Chinese Medicine theory.

The educational requirement cited in the WEAMA proposal only reflects the standards of training for candidates with no training in western medicine, acupuncture and Chinese Herbal therapy, which accounts for the criteria for a minimum of 1,500 hours and 2,000 hours of training and accounts for a 3-4 year training requirement.

The education and training currently available to Nurse Practitioners in WA State to meet the approved 300 hour acupuncture training requirements established by the NCQAC in 2017, includes the same level of training in theory included in the Master's degree program for Licensed Acupuncturist and over 100 hours of clinical and practicum experience to insure clinical competency, is accredited by the ANCC, and requires 18 months of training which is over 50% of the time required to complete a Master's degree in Acupuncture. In addition, continuing education opportunities remain available to graduates that will meet the same criteria for license renewal and Continuing Education (CE) credits required to renew licensure as an NP.

The training program currently available to NP in WA State is approved and accredited by the ANCC for 360 CE credits with the attached curriculum and training criteria.

The nature and duration of the training includes a substantial amount of supervised practicum training and 100 hours of clinical observation by a licensed acupuncturist to insure competency and is required for training certification.

Based on the existing training program and the criteria already established by the NCQAC, it is my opinion that the WEAMA proposal for a sunrise review be either changed to reflect and acknowledge the decisions of the NCQAC or revoked.

Dr. Fujio McPherson

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Washington State DOH Sunrise Review: Written Comments  
Re: Proposal to Increase Scope of Practice for Acupuncture and Eastern Medicine

Shannon Long, PT, DPT

Thank you for considering written comments during the WA DOH Sunrise Review process for proposed expansion of Acupuncture and Eastern Medicine Scope of Practice in include 'dry needling' and 'intramuscular needling'.

As a licensed, practicing Doctor of Physical Therapy for over 10 years, and having practiced in multiple US states which permit PTs to practice dry needling, I find it a complete detriment to the healthcare consumers of Washington state to allow one profession to monopolize a tool (monofilament needle) as is being proposed here. In our known national opioid epidemic, the thought of limiting non-pharmaceutical options for patients seems quite backwards regarding taking strides towards combating this crisis. It seems the applicant party is misunderstanding the intent of the Department of Health Sunrise Review process, to *advance practice scope and innovations in healthcare*, NOT to restrict other professions with inherent exclusivity of a modality or tool for purposes of financial gain. **I strongly oppose the current proposal to increase acupuncture scope of practice to include 'dry needling' and 'intramuscular needling'.**

I echo my colleague, Paul Killoren, PT, DPT, when he states:

*The applicant party's attempt to adapt all needling procedures (any use of a filiform needle) as practically defined as 'acupuncture' is not only unprecedented and categorically false, but anti-competitive and ultimately harmful to multi-disciplinary methodological advancement and healthcare consumer access. Again, it is worth citing over 40 US states have legislatively allowed physical therapists and chiropractors the ability to adapt dry needling into their scope of practice as decidedly unique from acupuncture. In 2018, a federal anti-trust lawsuit ruling between the North Carolina Acupuncture Licensing Board (NCALB) and North Carolina Board of Physical Therapy Examiners determined that dry needling is unique from acupuncture, that it is within the scope of physical therapy practice, and acupuncture efforts to restrict this physical therapy practice violate anti-trust regulations. Furthermore, the contention that other therapeutic professions lack adequate training and knowledge to have the ability to use filiform needles is absurd considering the academic and clinical curricula for these doctoring professions (DPT, DC, MD) is extensively more than the master's level training of the applicant group -- specifically education in anatomy, neuroanatomy, histology, physiology, standard precautions, critical inquiry, orthopedic and neuromusculoskeletal management.*

Thank you for considering commentary on this topic and denying the current proposal from acupuncture and eastern medicine scope of practice.

Shannon Long, PT, DPT

Tom Schaaf, MD, MHA  
*President* July 29, 2019

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**Katie Wolt**  
Washington State Department of Health, Sunrise Reviews  
P.O. Box 47850  
Olympia, WA 98504

Dear Ms. Wolt:

On behalf of the Washington State Medical Association (WSMA) and our more than 11,000 physician and physician assistant members, we appreciate the opportunity to comment on the Department of Health's (DOH) Sunrise Review concerning acupuncture and eastern medicine scope of practice. While the WSMA supports and encourages the use of integrative modalities like acupuncture, especially in the context of pain management, we have serious patient safety concerns with the proposed scope expansions as currently drafted.

**The WSMA opposes permitting acupuncturists to diagnose and treat disease outside of the specific context of eastern medicine.**

The WSMA acknowledges that under RCW 18.06.005, acupuncturists currently treat and diagnose disease by "drawing upon the experience, learning, and traditions originating in East Asia." As currently drafted, the Sunrise Review would create a massive scope expansion by permitting acupuncturists to diagnose and treat disease outside of that specific context (page 1, line 16). Acupuncturists lack sufficient education and training to enable them to safely diagnose and treat disease outside of traditions originating in East Asia. The WSMA requests this language be stricken or clarified.

**The WSMA opposes permissive language that provides for a major expansion of acupuncturist scope of practice.**

Page 1, line 13 of the Sunrise Review defines acupuncturist scope of practice as "a variety of traditional and modern therapeutic treatments including, but not limited to..." This language is too broad and offers no boundaries with respect to acupuncturists' education and training. Procedures and treatments should be referenced specifically.

**The WSMA opposes broad use of local anesthetics.**

Page 2, line 27 adds "local anesthetics" to the list of substances that may be used for point injection therapy. This language could be interpreted to mean local anesthetics may be injected

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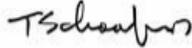
simply for their own value, rather than to assure a pain free experience while the acupuncturist is injecting other substances. Note that "local anesthetics" is referenced on line 31 in the questionable context of "emergency purposes for patient care and safety." In the interest of patient safety, the WSMA strongly recommends redrafting this section to limit the use of local anesthetics to only appropriate and specific circumstances.

**Patient safety.**

On page 4, line 9 we recommend inserting "The rules must specify circumstances where oxygen and epinephrine must be on site and those where it is optional." Several substances used in the practice of acupuncture may cause allergic reactions in some patients and oxygen and epinephrine should be readily available.

Thank you for the opportunity to share our concerns. Should you have further questions, don't hesitate to contact Billie Dickinson at [billie@wsma.org](mailto:billie@wsma.org). We look forward to working with the DOH and other stakeholders to remedy these concerns.

Sincerely,



Tom Schaaf, MD  
WSMA President



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## INTRODUCTION

The Physical Therapy Association of Washington (PTWA) represents physical therapists and physical therapist assistants across Washington. Currently, there are approximately 7500 licensed physical therapists and 2450 licensed physical therapist assistants in Washington.

In its applicant report, the Washington Acupuncture and Eastern Medicine Association (WAEMA) states that the proposed legislation is necessary to protect the public so that patients understand the practice of acupuncture. The bill amends the definition of acupuncture by further defining the meridians and acupuncture points on the body that may be stimulated by a filiform needle. Specifically, the proposed bill adds "trigger points, intramuscular needling, and dry needling" to the definition of acupuncture.

### WAEMA'S PROPOSAL DOES NOT MEET THE SUNRISE CRITERIA

RCW 18.120 establishes the criteria for applicants to meet when presenting an application for a sunrise review. Specifically, applicants must define the problem and why regulation is necessary; the efforts to address the problem before seeking a sunrise review; alternatives considered; the benefit to the public; and the extent to which the public may be harmed by the regulation.

In these comments, PTWA will show that:

- This legislation is not necessary
- The public will be harmed by the regulation
- This legislation is a violation of antitrust laws

### WAEMA'S PROPOSED LEGISLATION IS NOT NECESSARY

#### *There is no patient confusion regarding acupuncture and dry needling*

Several times in the applicant report WAEMA cites confusion by the public on who is inserting filiform needles for therapeutic purposes, and asserts that this confusion will lead to potential harm to patients. The applicant report states:

The potential harm to the public is when practitioners are not adequately trained or licensed to practice acupuncture in the state and the consumer becomes confused about what kind of treatment they are receiving and whether it is by a licensed practitioner with the treatment (acupuncture) within their scope of practice.

There is no evidence, however, that the public is confused about this practice. First, an analysis of the definitions of physical therapy and the definition of acupuncture or Eastern Medicine clearly shows the fundamental differences in these two professions.

Section 1 of WAEMA's proposed legislation supports the assertion that acupuncture and Eastern medicine are distinct systems of medicine. The legislation creates a new definition of the practice of acupuncture or Eastern medicine as:

A holistic system of medicine often referred to as traditional Chinese medicine, Eastern medicine, and other terms, which includes a variety of traditional and modern therapeutic treatments including, but not limited to, the practice of acupuncture techniques and herbal medicine, to maintain and promote wellness, prevent, manage, and reduce pain, treat substance use disorder, and diagnose and treat disease.

That section continues with a list of modalities that are included as the practice of acupuncture or Eastern medicine, including the "use of presterilized disposable needles such as filiform needles, and other needles, syringes, or lancets to directly and indirectly stimulate meridians and acupuncture points, including ashi points, motor points, trigger points, intramuscular needling, dry needling, and other non-specific points throughout the body."

This proposed definition clearly shows that acupuncture and Eastern medicine are based in traditional Chinese medicine. Acupuncture is used to stimulate acupuncture points and meridians to restore energy flow within the body. It is a holistic approach to patient care with the treatment of a wide variety of patient conditions and diseases.

In contrast, the definition of physical therapy found at RCW 18.74.010(10) reads, in part,

"Practice of physical therapy" is *based on movement science* and means:

(a) Examining, evaluating, and testing individuals with mechanical, physiological, and developmental impairments, functional limitations in movement, and disability or other health and *movement-related conditions* in order to determine a diagnosis, prognosis, plan of therapeutic intervention, and to assess and document the ongoing effects of intervention;

(b) Alleviating impairments and *functional limitations in movement* by designing, implementing, and modifying therapeutic interventions that include therapeutic exercise; functional training related to balance, posture, and movement to facilitate self-care and reintegration into home, community, or work; manual therapy including soft tissue and joint mobilization and manipulation; therapeutic massage; assistive, adaptive, protective, and devices related to postural control and mobility except as restricted by (c) of this subsection; airway clearance techniques; physical agents or modalities; mechanical and electrotherapeutic modalities; and patient-related instruction; (emphasis added)

Physical therapy is based on movement science and is focused on treating functional impairments, movement-related impairments and injuries, and is based in Western medicine. Physical therapists treat a wide range of medical conditions including:

- Cardiopulmonary conditions
- Hand therapy
- Musculoskeletal conditions such as low back pain
- Neurological conditions such as stroke, Parkinson's disease, and traumatic brain injury
- Pediatric conditions such as cerebral palsy and muscular dystrophy
- Sports-related injuries

- Wound care
- Women's health and pelvic floor dysfunction

In summary, the laws of acupuncturists and physical therapists demonstrate very different and distinct practice acts, such that a patient would not be confused about the treatment rendered by either professional.

Furthermore, a recent administrative law case in Florida demonstrates that there is no confusion between treatment by a physical therapist and treatment by an acupuncturist.

In Florida State Oriental Medicine Association (FSOMA) vs. the Department of Health, Board of Physical Therapy and the Florida Physical Therapy Association (FPTA) (case number 18-2508RP, FSOMA argued that there is confusion between acupuncture and dry needling. However, the administrative court found that FSOMA did not provide any evidence of any such confusion from the 35 U.S. jurisdictions that allow physical therapists to perform dry needling. The Board of Physical Therapy cited evidence that physical therapists explain the practice of dry needling to patients so that no such confusion occurs.

#### THE PUBLIC WILL BE HARMED BY WAEMA'S PROPOSED LEGISLATION

##### **WAEMA's proposed legislation will harm the public by blocking access to dry needling and intramuscular needling by other licensed healthcare providers**

WAEMA is very clear in its applicant report that this legislation is an attempt to define the terms "intramuscular needling" and "dry needling" such that no other profession may use dry needling or intramuscular needling in their practice, or stimulate these points without first being licensed as an acupuncturist. It states:

*"This is not intended to limit other professions from gaining access to acupuncture techniques legislatively with appropriate training, it only assures that these terms will also be understood as the practice of acupuncture, not to be superseded or disallowed by alternative definitions that may arise in the future (emphasis added)."*

This attempt ignores the fact that dry needling and intramuscular needling are different from acupuncture and are currently practiced by healthcare providers in Washington and across the country who are not licensed acupuncturists. By seeking to define dry needling and intramuscular needling as acupuncture, WAEMA cuts off access to these techniques by other qualified healthcare providers who are not acupuncturists. It essentially forces these otherwise-qualified providers to seek an additional license as an acupuncturist, even though they do not want to perform acupuncture but merely want to provide the best care for their patients using all of the techniques they were trained to use.

##### **Overlap of scopes of practice common among healthcare providers**

It is not uncommon for healthcare providers' scope of practice to overlap. In fact, overlap is essential to give patients a variety of providers when seeking treatment. In Washington, for example, physical therapists, chiropractors, osteopaths, medical doctors and naturopaths all have joint manipulation in their respective scopes of practice. However, a physical therapist performing joint manipulation is not practicing medicine or chiropractic simply because they are performing joint manipulation.

Similarly, physical therapists and occupational therapists both have exercise and wound care management in their respective scopes of practice. Massage therapists, East Asian medicine practitioners, physical therapists and many other practitioners may all perform manual treatments or “massage” techniques to muscles. This does not mean that physical therapists, occupational therapists, and acupuncturists are practicing massage therapy. Overlap is to be expected between disciplines in order for there to be access to high quality care.

In fact, the publication “Changes in Healthcare Professions Scope of Practice: Legislative Considerations” asserts that no one healthcare profession owns a skill or modality. They can be shared if the profession has the education and training and appropriate legal authority. Further, a profession is not defined by one modality. Physical therapy is defined as “the care and services provided by or under the direction and supervision of a physical therapist licensed by the state.” The physical therapy practice act goes on to define the practice of physical therapy using terms such as “examining,” “evaluating,” “testing,” “functional limitations in movement,” not as a laundry list of treatment techniques. In fact, PTWA pursued an overhaul of the practice act in 1999 to modernize the statute to reflect the body of knowledge of a physical therapist, not a list of modalities.

Finally, the American Medical Association recently accepted an application from the APTA and the American Chiropractic Association (ACA) to develop a new CPT code for dry needling. This new code will be found under the surgery codes, as non-time based, and cross referenced under the Physical Medicine and Acupuncture sections. Acupuncture associations were involved in this process and agreed to this code being under both physical medicine and acupuncture. This demonstrates that acupuncture associations agree that dry needling is a modality to be shared among health care providers.

#### **Patients need access to dry needling from multiple providers to ensure quality care**

Dry needling is a technique that originates in Western medicine. Dry needling uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues for the management of neuromusculoskeletal pain and movement impairments. (APTA Resource Paper 2013). Dry needling is used to treat dysfunctions in skeletal muscle, fascia, and connective tissue, diminish persistent peripheral nociceptive (pain) inputs, and reduce or restore impairments of body structure and function leading to improved movement and function (APTA Resource Paper 2013).

Dry needling has been shown to reduce pain and improve outcomes in patients with myofascial pain. Research in the medical community on the benefits of dry needling date back to the 1970s and 80s. Studies on patients with chronic low back pain showed that patients who received dry needling returned to work more quickly than those in the control group who had not received dry needling (Gunn, 1980).

Evaluations of the effectiveness of dry needling on patients with neck and shoulder pain showed that dry needling reduced patients’ pain, improved range of motion, and improved physical and emotional well-being and mood (Gerber 2015).

Dry needling has also been shown to be effective in costly chronic conditions such as fibromyalgia. A study in the journal “Rheumatology International” evaluated the short-term efficacy of dry needling therapy in patients severely affected by fibromyalgia. At the end of treatment, the experimental group

showed significant improvements in most tests, including pain, fatigue, and global subjective improvement. Six weeks after the end of the treatment, the dry needling group still showed significant improvements in most tests (Casanueva 2014).

Dry needling can have additional benefits in reducing spasticity in patients with neurologic impairments. A study in the "Journal of Manipulative Physiologic Therapy" found that patients who had had a stroke and who underwent one session of dry needling in their calf and shin muscle had reduced spasticity and decreased pressure sensitivity after the intervention (Salom-Moreno 2014). This type of benefit can then be immediately translated to therapeutic exercise and gait training during a physical therapy session.

Many patients with myofascial pain and trigger points are already receiving physical therapy or are referred to physical therapy for treatment of their muscle imbalance and pain. In states that allow physical therapists to perform dry needling, patients who receive dry needling during their treatment have received it as part of their overall physical therapy plan of care, not as an individual therapy. Thus, dry needling enhances the success of their overall physical therapy treatment.

#### **Patients need access to dry needling from multiple providers for cost effective care**

Dry needling and intramuscular needling are modalities that are part of the physical therapy scope of practice in 34 states, plus the District of Columbia. Dry needling is also performed by physical therapists in all branches of the United States military. Other practitioners who perform dry needling include physiatrists, orthopedic doctors, and naturopaths. Limiting this technique to acupuncturists will limit the patient's choice of providers as well as being potentially cost prohibitive to patients.

Musculoskeletal conditions are currently among the costliest to manage. Low back pain (LBP) (acute, subacute and chronic) is a common condition and the leading cause of disability in the United States as of 2010. At least 80% of adults will have LBP at some point in their life and approximately 20-30% of the adult population has LBP at any given time. Expensive, non-conservative modalities (e.g., imaging, opioids and spinal injections) are often used for acute LBP in the absence of a clear indication for those services, further driving up LBP costs.

The current high cost of treating LBP and related musculoskeletal conditions make them a major source of concern to all healthcare stakeholders, especially employers and other purchasers such as the Washington State Department of Labor and Industries. The total direct healthcare costs attributable to LBP in the United States were estimated to be \$26.3 billion in 1998.

Access to dry needling treatment improves outcomes and facilitates patient participation with other physical therapy techniques like manual therapy and active exercise. Many patients are *already receiving physical therapy care* and prefer to get treatment within the western medical model. If physical therapists are not able to utilize this technique, patients will require many more sessions of physical therapy to treat their condition or the patient may need additional treatment from another healthcare practitioner.

WAEMA'S LEGISLATION IS A VIOLATION OF THE ANTITRUST LAWS  
OF THE UNITED STATES

*North Carolina dry needling lawsuits and other antitrust activity*

Federal antitrust laws, beginning with the Sherman Act in 1890, and continuing with the Federal Trade Commission Act, which created the Federal Trade Commission, and the Clayton Act, prohibit conduct that unreasonably restrains competition through the creation of a monopoly. This monopolistic behavior suppresses competition and is anti-consumer.

The issue of antitrust and the practice of dry needling have been addressed by the courts. In late 2015, the North Carolina Physical Therapy Association (NCPTA) brought a federal antitrust lawsuit against the North Carolina Acupuncture Board (Board) on behalf of physical therapists and their patients. That lawsuit asserted the Board's efforts to prevent PTs from engaging in dry needling, efforts that included issuing "cease and desist" letters to PTs who perform dry needling, as well as threatening PTs with Class 1 misdemeanor charges for noncompliance, violated federal antitrust laws.

After four years of litigation, in March 2019, the parties agreed to a settlement in federal district court that acknowledges dry needling as a part of the physical therapy scope of practice in North Carolina. This agreement applies to current and future acupuncture boards, and included a monetary settlement to the plaintiffs.

Dry needling was also an issue in a September 2015 suit filed against the North Carolina Physical Therapy Board by the North Carolina Acupuncture Board, which sought to have a county superior court declare that dry needling is outside the scope of PT practice. That suit eventually wound up in the state's Supreme Court, which upheld the lower court's ruling that dry needling was part of physical therapy practice in the state.

These examples, both on point with WAEMA's sunrise application, show that efforts by acupuncturists to restrict the term "dry needling" solely to the acupuncture scope of practice are not supported by the courts.

The United States Supreme Court has also weighed in on anti-trust cases, most recently holding in *North Carolina Board of Dental Examiners v. Federal Trade Commission* (574 U.S. \_\_\_\_ (2015)) that the North Carolina Board of Dental Examiners was composed of market participants and was not supervised by the state. As such, the Board could not claim state anti-trust immunity and prevent non-dentists from offering cosmetic teeth whitening services and products.

680 Dugwalla Road  
Oak Harbor, WA 98277

7/16/19

Dear Ms. Wolt,

Thank you so much for your work with Sunrise Reviews. The Physical Therapy Association of Washington sent out an email today with the request from Representative Cody to expand the scope of acupuncture practice. I read through the request from legislature, applicant report, applicant report exhibits, follow-up questions, draft bill, + notice of public hearing.

I was disturbed in reading the documents that our profession of physical therapy was written about in at best a simple way and at worst a defaming manner. With regard to intramuscular needling, also called dry needling in other states, 47 states allow physical therapists to dry needle. I recently moved to WA from NC where I had a cash-based dry needling business. My treatment was safe + effective. I have a Doctor of Physical Therapy and I spent 2 years dissecting in a cadaver lab for my master's

(1)

of physical therapy. My training in dry needling came after I was licensed and I was trained at Myopain Seminars in Bethesda, MD, the very place that Dr Janet Travell practiced. The acupuncture/Rep Cody documents cite Dr Travell as part of their research backing. Of note, she was a Western Medicine doctor, a cardiologist, and President Kennedy's MD. Her work on myofascial trigger points has been taught and used by many professions including Massage + physical therapists. The intramuscular needling is derived from her work, not acupuncture Chinese medicine. I believe the language in the documents is muddy, confusing the two. Representative Cody refers to her training at one point, and she is a nurse.

It is important for the integrity of the Washington Department of Health to support all health care professions as we are licensed and trained. As you know, Ben Boyle and the PT legislative team have provided extensive research reviews and changes to PT practice re: intramuscular therapy in response to Sunrise Review requests + in efforts to communicate fairly with other providers.

We as physical therapists do not defame or limit the practice of other professions. Although the documents state that the intent is not to limit other professions' practice but to widen the acupuncture scope, the documents directly name our profession and assume our training. There is a claim that doing myofascial needling work is acupuncture, which is simply NOT true as deemed by other medical professionals + states.

NC recently underwent legislation that was taken to a federal level because acupuncturists tried to limit physical therapists from performing our jobs. This is the same battle. Like all other states who have had to address this issue, NC PTs won and the acupuncturists had to pay >100,000 dollars due to defrauding our profession. It's against article 5 of the constitution for acupuncturists to ask legislation be passed that restricts other professions from doing what we can do to ~~help~~ help patients. We want to provide patients with as many options for pain relief, especially in the setting of opioid crisis. I request that the acupuncture documents remove all written claims about physical therapy

and claims that acupuncture essentially "owns" myofascial techniques such as intramuscular therapy/needling.

Twenty of my NC patients wrote intramuscular therapy testimonies supporting their success with physical therapist (me!) needling. I can email these to you if you like. Sometimes hearing from a patient directly communicates what health care really needs to be about.

Thank you,

Miranda Bunge, PT, DPT, CMTA  
miranda.bunge@gmail.com

P.S. I did see that Rep Cody chose to use some research written by PTs in her source list. PTs have done a lot of evidence-based research about physical therapy + dry needling.