Pilot: Acupuncture for Chronic Pain in the Vermont Medicaid Population
Robert Davis, MS, LAc
Overview of Presentation

Background  Design  Results  Context
VT Senate Committee on Health and Welfare
2015-16 Session

Act 173 “Opioid Bill” - $200,000 - pilot study to assess acupuncture as an adjunct therapy for the treatment of chronic pain in the Vermont Medicaid population. “social, psychological and occupational function”
Opioid Crisis

“...an epidemic of prescription opioid abuse, overdoses and deaths – and no demonstrable reduction in the burden of chronic pain.”

Opioid Crisis - How did we get here?

Risk of continued opioid use increases at 4-5 days

Likelihood of continuing to use opioids

Source: Centers for Disease Control and Prevention
Credit: Sarah Frostenson
How did we get here?

**Opioid Crisis** - How did we get here?

**Intensity of Chronic Pain — The Wrong Metric?**

Jane C. Ballantyne, M.D., and Mark D. Sullivan, M.D., Ph.D.

The New England Journal of Medicine

- Acute pain and end of life pain ➔ “titrate to effect”
- Pain = “fifth vital sign” = compassionate care
- Habituation = ↓quality of life, ↓function, ↑addiction
- Acute pain and end of life pain ≠ chronic pain
  - brain regions – pain centers ➔ emotion and reward centers
  - biological, psychological and social differences
Opioid Crisis - Where do we go now?

National Pain Strategy
A Comprehensive Population Health-Level Strategy for Pain

- Multiple measures needed - complex causes and consequences of pain.
- Interdisciplinary and multimodal treatments
- Biopsychosocial approach
- Treat not only pain intensity, but distress, disability and suffering.
How can acupuncture help?

Very Safe
Effective for pain
Biopsychosocial Impact
Acupuncture is Safe

Supported via:

- Randomized Controlled Trials/Systematic Reviews
- Patient & Practitioner reported Prospective Surveys

Adverse Events are common but rarely serious

58% minor bleeding/bruising

Serious Adverse Event rate is very low


Acupuncture is Effective for Chronic Pain

**Background:** Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for 4 chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

**Methods:** We conducted a systematic review to identify randomized controlled trials (RCTs) of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17,922 patients analyzed.

**Conclusions:** Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

Acupuncture is not just a needling procedure, it is a biopsychosocial approach.

Self-help advice as a process integral to traditional

Individualised self-help advice ... an integral part of the treatment ... for patients with low back pain.

movement, exercise and stretching to move ‘qi stagnation’ rest in cases of ‘qi deficiency’
diet when the digestive system was compromised protection from the elements where indicated by the diagnosis

longer-term benefits require the active participation of patients in their self-care.

Simplified concepts from acupuncture theory, such as ‘stagnation’ and ‘energy’, are employed as an integral part of the process of care, in order to engage patients in lifestyle changes, help them to understand their condition, and to see ways in which they can help themselves.
Overview of Presentation

Background  Design  Results  Context
Pilot Design and Rationale

PROCESS:
• Analysis of the goals, resources and timeline provided by Act 173
• Review of literature
• Consultation with several leading acupuncture trialists

DESIGN:
• prospective pragmatic intervention design
• thoroughly described in progress report and publication
MAIN QUESTION: Does the process of receiving acupuncture treatment from the existing Vermont workforce of Licensed Acupuncturists improve health outcomes for Vermont Medicaid patients with chronic pain?

POPULATION
VT medicaid enrollees with chronic pain

INTERVENTION
Up to 12 treatments by a VT licensed acupuncturist

COMPARISON
Pre- and post-test measurements, no controls

OUTCOMES
PROMIS questionnaires
DVHA utilization analyses
Descriptive data
TRIAL DESIGN

Explanatory
- Standardized
- Homogenous
- Objective
- Internal

Pragmatic
- Close to usual care
- Heterogeneous
- Patient centered
- External

Treatment

Patients

Outcomes

Validity

Diagram shows a spectrum from Explanatory to Pragmatic, with different criteria for each end:
- **Explanatory**:
  - Standardized
  - Homogenous
  - Objective
  - Internal

- **Pragmatic**:
  - Close to usual care
  - Heterogeneous
  - Patient centered
  - External
Acupuncture for Chronic Pain in the Vermont Medicaid Population

Recruitment
- Chittenden Co.
- Montpelier
- White River Jct

Screening
- Telephone
- Research Asst.

Face to Face
- Research Asst.
- Informed Consent
- Pre-Questionnaires
- $25 compensation
- Referral to L.Ac.’s
Treatments
Up to 12 txs in 60 days
Provided in local L.Ac. Offices
Accrue new patients Feb-Mar.
Latest enrollment date – Mar.31
Last tx Date May 31

Face to Face
Research Asst.
Post-Questionnaires
$25 compensation

Assessment
Pre-Post Change
Utilization Review (60/60/60)
Descriptive data
Overview of Presentation

- Background
- Design
- Results
- Context
156 Total Patients entered pilot
29% males, 71% females
Descriptive Statistics:

Patients

Distribution by Age

- 18-34: 22%
- 35-50: 38%
- 51-70: 38%
- 70+: 2%
Descriptive Statistics: distribution by region

Chittenden County
  15 acupuncturists, 578 treatments

Washington County
  10 acupuncturists, 595 treatments

Windsor County
  3 acupuncturists, 101 treatments

Total = 1274 treatments by 28 Licensed Acupuncturists in three regions of Vermont
72% of patients received at least 6 treatments.

No significant differences were detected between baseline outcome measures and patients who received or did not receive treatments.
**Participant Chief Pain Complaints**

- **Back**: 30%
- **Muscle/joint - other**: 15%
- **Neck**: 8%
- **Shoulder**: 7%
- **Headache**: 7%
- **Knee**: 7%
- **Ankle/Foot**: 5%
- **Abdominal**: 3%
- **Hip**: 3%
- **Hand**: 3%
- **ElbowArm**: 3%
- **Sciatica**: 2%
- **Jaw**: 2%
- **Carpal Tunnel**: 1%
- **Other**: 4%
Objective measurements before and after acupuncture treatments

PROMIS® (Patient-Reported Outcomes Measurement Information System)

- publicly available, highly reliable, precise measures of patient-reported health status for physical, mental, and social well-being.

- 10 years of investment and development from NIH

- Developed and validated with state-of-the-science methods to be psychometrically sound and to transform how life domains are measured

- Created to be relevant across all conditions for the assessment of symptoms and functions

- The work surrounding PROMIS has resulted in over 400 publications. More than 100 NIH grants have supported investigations using PROMIS instruments.

- We measured 8 domains: Pain Intensity, Pain Interference, Physical Function, Fatigue, Sleep Disturbance, Anxiety, Depression, Social Isolation
RESULTS: Three Important Points of Reference

1) How did our patients compare with a relevant reference population?

PROMIS measures are standardized to center around the US general population or in the case of Pain Intensity, around people with pain from the US general population and pain support groups.

*By comparing our patients against a reference population, we learn how “sick” or “healthy” they are.*

50 = US population mean
RESULTS:
Baseline (pre-treatment) percentile scores referenced to normative population*

*normative population is US population for all measures except Pain intensity which uses the population of people in pain or in pain support groups.

Fatigue - 88th
Anxiety - 87th
Depression - 82nd
Sleep Disturbance - 79th
Pain Intensity - 70th
Social Isolation - 63rd
RESULTS: 
Three Important Points of Reference

2) How do our patients compare with themselves before and after treatment?

By comparing our standardized PROMIS measures taken prior to treatment with the measures taken post-treatment, we learn whether they improved, stayed the same, or got worse. Statistical tests help us determine if any observed changes are likely to be due to chance or not.

Did the patients improve? Was it random or systematic?

50 = US population mean
Change in PROMIS scores (pre vs. post-treatment)

Physical Function
10th to 21st percentile
Effect size .44
Paired T-test p<0.01

Effect size (ES): .2 = small
.5 = moderate
.8 = large

50 = normative population mean
Normative population is US population
for all measures except Pain Intensity
which uses the US population of people
in pain or in pain support groups

1 std dev.

T-score

Sleep Disturbance
79th to 56th percentile
ES .64
Paired T-test p<0.01

Fatigue
88th to 69th
ES .71
Paired T-test p<0.01

Pain Interference
94th to 82th percentile
ES .61
Paired T-test p<0.01

Depression
82nd to 70th
ES .42
Paired T-test

Pain Intensity
70th to 58th
ES .35
Paired T-test p<0.01

Anxiety
87th to 77th
ES .4
Paired T-test p<0.01

Social Isolation
63rd to 55th
ES .2
Paired T-Test p=.002

T-score

percentile
Three Important Points of Reference

3) Are the observed changes large enough to be clinically meaningful?

Clinically meaningful differences are differences that are large enough and important enough to make a difference in a patient’s life.

They are also called

Minimally important differences - “the smallest change in score which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient’s management.”

Important to consider when making policy decisions.
3) Are the observed changes large enough to be clinically meaningful?

**Metrics we can use:**

By comparing our observed changes against:

a) **standardized metrics of effect size** and
b) normative thresholds in reference populations

we can estimate how meaningful these changes are likely to be to patients.

**standardized metrics of effect size**

Effect size: 
- .2 = small
- .5 = moderate
- .8 = large

T score – 10 points = 1 SD
RESULTS:
Three Important Points of Reference

3) Are the observed changes large enough to be clinically meaningful?
By comparing our observed changes against:
   a) standardized metrics of effect size and
   b) normative thresholds in reference populations
      we can estimate how meaningful these changes are likely to be to patients.

“normal” threshold = within 1 standard deviation from mean of the non-disturbed reference group

T score – 10 points = 1 SD
Change in PROMIS scores (pre vs. post-treatment)

- **Physical Function**: 10th to 21st percentile, Effect size .44, Paired T-test p<0.01
- **Depression**: 82nd to 70th percentile, ES .42, Paired T-test p<0.01
- **Pain Interference**: 94th to 82nd percentile, ES .61, Paired T-test p<0.01
- **Sleep Disturbance**: 79th to 56th percentile, ES .64, Paired T-test p<0.01
- **Fatigue**: 88th to 69th percentile, ES .71, Paired T-test p<0.01

Effect size (ES):
- .2 = small
- .5 = moderate
- .8 = large

50 = normative population mean
Normative population is US population for all measures except Pain Intensity which uses the US population of people in pain or in pain support groups

Pain Intensity: 70th to 58th percentile, ES .35, Paired T-test p<0.01
Anxiety: 87th to 77th percentile, ES .4, Paired T-test p<0.01
Social Isolation: 63rd to 55th percentile, ES .2, Paired T-Test p=.002

T-score
OTHER OUTCOMES
Pre-intervention questionnaire

• Please list or attach a list of any doctor-prescribed medications or medications you purchased yourself (e.g. Advil, Tylenol, Aleve, etc.) that you take to help manage your pain. Include the dosage and how often you have taken during the past week.

• Do you experience side effects from your medications? If so, please describe.

• Has your pain impacted your work? For example, has it affected the quality of your work or the number of hours you are able to work?
OTHER OUTCOMES
Post-intervention questionnaire

• If you take any doctor-prescribed medications or medications you purchased yourself (e.g. Advil, Tylenol, Aleve, etc.) for your pain, please list the medications, dosage and frequency of use during the past week. Has this changed as a result of your acupuncture treatment?

• Has the quality of your work or the number of hours you are able to work changed as a result of your acupuncture treatment? If so, please describe.

• Would you recommend acupuncture to someone else with chronic pain?

• Is there anything else you would like Vermont health care policy makers to know about your experience with acupuncture?

• Would you be willing to discuss your experience in this study with a research assistant? If so, please provide your name and telephone number.
43% of those using medications experienced unwanted side effects including “upset stomach, nausea, drowsiness, constipation, fatigue, dry mouth, grogginess, loopiness, forgetfulness.”
Medication Users (N=82)

- Decreased medication use after acupuncture: 57%
- No Change: 43%
Decreased opiate use after acupuncture: 32%
No Change: 68%
Sample Quotes – medication use

• “less oxycodone and ibuprofen”
• “50% less hydrocodone”
• “much less Tramadol and no Tizanadine since acupuncture”
• “only 1 pill of muscle relaxer instead of 2”
• “has not taken any oxycodone since treatment”
• “less morphine, docs taking me down on oxys slowly”
• “off tramadol and aleve/tylenol/ibuprofen used half as often as before”
• “less lyrica, tramadol as needed but haven't needed it”
97% of pre-treatment respondents (n=156) said their pain had affected their work.

Post-treatment:
Has the quality of your work or the number of hours you are able to work changed as a result of your acupuncture treatment? (N=114)
Sample Quotes - Work Status

• “Don’t work, but helped with household chores.”
• “can work 30 hrs a week and was working none before!”
• “Quality of work increased- much more settled and engaged”
• “added 10 hrs per week !”
• “No Improvement, but I only had one treatment.”
• “more focused”
• “Can work more, more focus, feel clearer/more productive”
• “been out with severe headaches less now”
• “can stand for multiple 9 hr shifts in a row, less pain after work”
• “could previously only give 2 massages/day but can go back to 3/day now”
• “got a job!”
• “I work a physically demanding job, and I have been able to return to work”
Would you recommend acupuncture to someone else with chronic pain?

- Yes: 96%
- No: 2%
- Maybe: 1%
- With Hesitation: 1%
“Is there anything else you would like Vermont health care policy makers to know about your experience with acupuncture?”

247 patient comment strands were identified and categorized by theme by two independent raters:

**Comment Strand Themes**

- Physical Improvements: 31% (77)
- Functional/Behavioral Improvements: 29% (72)
- Psycho-emotional Improvements: 24% (60)
- Other: 11% (28)
- No Change: 4% (9)
- Symptom Aggravation: <1% (1)
Themes from Patient Comments

Physical Symptom Improvements
• Decreased pain – 71
• Improvements in non-pain physical symptoms – 6

Functional/Behavioral Improvements
• Increased function/ability to perform activities of daily living – 50
• Increased energy - 17
• Decrease in use of other health services – 5

Psycho-emotional Improvements
• Increased sense of wellbeing - 18
• Positive changes in emotional states – 16
• Increased ability to relax – 15
• Increased options and hope – 4
Themes from Patient Comments

Psycho-emotional Improvements (con’t)
• Increased body awareness – 4
• Changes in thinking that increased ability to cope with pain – 3

Other
• Wished acupuncture treatments could continue – 19
• Change in beliefs about acupuncture – 5
• Felt listened to by acupuncturist – 4

No Change – 9

Symptom Aggravation - 1
Representative Patient Comments

- "My acupuncture was life changing... I saw and felt and continue to feel a marked difference in my pain and mental clarity. I believe it saved my life."

- "Acupuncture helped me to get my life back."

- "I was very skeptical about this treatment being effective. As the weeks went by, I noticed different changes taking place in my body: my digestive system functioned much better, so my diet improved; I required less sleeping medication because my sleep was better; my pain level was much decreased; I had more genuine energy; and most especially, I had better mobility. The mobility change enabled me to walk more in fresh air and increased my good energy level. A circle of reinforcements has made my life much better, more productive and happier. It has cut down my need for other medical interventions like physical therapy and medications for various ailments. People have noticed the outward improvement."

* Patient permission obtained to use photos. Photos and comments are decoupled.
Representative Patient Comments

• "I went to a regular doctor for over six years and my pain only became more intense and more frequent. This is the longest I've gone without pain or medication in well over a year.”

• “This is a very necessary way to treat pain. I am very allergic to many medications and during the study I was able to walk and do more without an allergic reaction”

• "I would consider the acupuncture treatment I received to be the most effective of every treatment option I've ever tried in my life at reducing my pain and increasing my quality of life, as well as the quickest in producing results. I was able to stop taking all my pain medications while receiving acupuncture and was even able to try a few physical activities (such as yoga) that have caused me pain in the past. I only wish I could continue to receive acupuncture as I believe it's the one treatment with results that would allow me to work full time... if I was able to continue treatments if/when my pain flared up again.”

* Patient permission obtained to use photos. Photos and comments are decoupled.
Representative Patient Comments

• "I literally went in there day one thinking it was quack science and now I desperately miss it."

• “Gained 2 hrs of sleep a night from the acupuncture because it helped me relax. 100% would recommend to anybody with pain”

• "I have received acupuncture before but it was the consistent treatments that I felt a shift happen in my healing process”

• "It has somewhat improved my quality of life. It has significantly reduced the frequency of migraine headaches and helped to reduce arthritis pain in my neck and shoulders. Was not effective for osteoporosis back pain or peripheral neuropathy in hands and feet pain.”

• “Makes huge difference in well being, physical and mental. Helps with pain, sleep, cognition”

• "If it had been covered, I may not of gotten [sic] so many scripts of narcotics and gotten addicted to opiates."

* Patient permission obtained to use photos. Photos and comments are decoupled.
Other Results

The acceptability and feasibility of making acupuncture more accessible to Vermonters with chronic pain appears to be high.

- Recruitment and enrollment goals were achieved much more quickly and with less effort than anticipated based on the norm for clinical trials. This suggests there is demand for acupuncture amongst Vermont Medicaid patients.

- One of the reasons for the high volume and speed of recruitment is that a majority of patients were referred by physicians. This suggests that the demand for and acceptability of acupuncture as a referral is high amongst the physician community in Vermont.

- There was no trouble recruiting acupuncture providers to participate in the study. This suggests that a significant proportion of the workforce of approximately 200 Licensed Acupuncturists in Vermont would be willing to serve this population if the reimbursement and administrative requirements were similar to pilot levels. (Providers were compensated at a rate similar to the BCBS and Workers Comp reimbursement rates.)
**Discussion**

**Strengths of study:**
Uses validated patient-centric outcome measures referenced to appropriate normative US populations.

Qualitative data provide important insight into patient values and experiences.

Data pertaining to the Medicaid population is relatively rare and therefore valuable. Acupuncture is usually used by patients with above average income and educational demographics.

**Pragmatic Design** – provides high confidence that results would generalize to Vermont health care system (VT Medicaid patients, VT Licensed Acupuncturists and VT referral sources.)

- Naturalistic enrollment mimics current insured patient practices.
- “real world” patient diversity – non-restrictive and heterogeneous pain diagnoses and complicated co-morbidities allowed
- Geographic diversity (treatments in three counties, patients from 11 counties)
- Practitioner diversity (not “cherry-picked” for experience or style of practice). Average duration of Vermont acupuncture license = 9.67 years, range = 8 months to 21 years
- Patients allowed to choose their own provider
Discussion

Limitations of study:

Potential confounders?
• The pilot design did not control for potential confounders to our results (e.g. the natural course of disease, regression to the mean, unknown variables). However, a significant body of randomized controlled trials provide some confidence that these potential confounders are unlikely to have changed our conclusions.

Long term effects?
• This pilot did not provide data regarding the long term effects of treatment. However, a meta-analysis of acupuncture patients with chronic pain suggests that approximately 90% of the benefit of acupuncture would be sustained at 12 months.
  (citation on next slide)
The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of patients with chronic pain.


..."effect sizes diminished by a non-significant 0.011 SD per 3 months after treatment ended."

"...suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months."

"Patients can generally be reassured that treatment effects persist. Studies of the cost-effectiveness of acupuncture should take our findings into account when considering the time horizon of acupuncture effects."
Overview of Presentation

Context
1. Risk/benefit – acupuncture vs. pharmaceuticals
2. Professional guidelines/recommendations
3. Reimbursement policies ➔ how pain is managed
Benefits vs. Risks/Side Effects
Comparing the benefits

Effect size estimates for pooled drug classes for treating insomnia suggest small to moderate effect sizes (placebo or wait list controls):

- .24 to .36 effect size – objective outcomes
- .21 to .41 effect size – subjective outcomes


Our acupuncture results: (percentile improvements)

- **Sleep Disturbance**: 23 points (.64 effect size)
- **Fatigue**: 19 points (.71 effect size)
- **Pain Interference**: 12 points (.61 effect size)
- **Depression**: 12 points (.42 effect size)
- **Pain Intensity**: 12 points (.35 effect size)
- **Physical Function**: 11 points (.44 effect size)
- **Anxiety**: 10 points (.40 effect size)
- **Social Isolation**: 8 points (.20 effect size)
Comparing the benefits

Effect size estimates for treating depression:
Antidepressants: 0.3 effect size - small effect (placebo controls)

World Psychiatry. 2017 Jun; 16(2): 181–192. PMCID: PMC5428172
Has the rising placebo response impacted antidepressant clinical trial outcome? Data from the US Food and Drug Administration 1987-2013

Our acupuncture results: (percentile improvements)
- Sleep Disturbance 23 points (.64 effect size)
- Fatigue 19 points (.71 effect size)
- Pain Interference 12 points (.61 effect size)
- Depression 12 points (.42 effect size)
- Pain Intensity 12 points (.35 effect size)
- Physical Function 11 points (.44 effect size)
- Anxiety 10 points (.40 effect size)
- Social Isolation 8 points (.20 effect size)
Comparing the benefits

Effect size estimates for treating pain intensity:

- Opioids for osteoarthritis pain: .79 ES - large effect
- NSAIDS for osteoarthritis pain: .29 ES – small effect
- Tylenol for OA or back pain: .14 ES – not meaningful

(Placebo controls)


Our acupuncture results: (percentile improvements)

- **Sleep Disturbance** 23 points (.64 effect size)
- **Fatigue** 19 points (.71 effect size)
- **Pain Interference** 12 points (.61 effect size)
- **Depression** 12 points (.42 effect size)
- **Pain Intensity** 12 points (.35 effect size)
- **Physical Function** 11 points (.44 effect size)
- **Anxiety** 10 points (.40 effect size)
- **Social Isolation** 8 points (.20 effect size)
Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain
A Systematic Review and Meta-analysis

Christina Abdel Shaheed, PhD; Chris G. Maher, PhD; Kylie A. Williams, PhD; Richard Day, MD; Andrew J. McLachlan, PhD

MAIN OUTCOMES AND MEASURES  The primary outcome measure was pain. Pain and disability outcomes were converted to a common 0 to 100 scale, with effects greater than 20 points considered clinically important.

RESULTS  Of 20 included RCTs of opioid analgesics (with a total of 7925 participants), 13 trials (3419 participants) evaluated short-term effects on chronic low back pain, and no placebo-controlled trials enrolled patients with acute low back pain. In half of these 13 trials, at least 50% of participants withdrew owing to adverse events or lack of efficacy. There was moderate-quality evidence that opioid analgesics reduce pain in the short term; mean difference (MD), −10.1 (95% CI, −12.8 to −7.4). Meta-regression revealed a 12.0 point greater pain relief for every 1 log unit increase in morphine equivalent dose ($P = .046$). Clinically important pain relief was not observed within the dose range evaluated (40.0-240.0-mg morphine equivalents per day). There was no significant effect of enrichment study design.

CONCLUSIONS AND RELEVANCE  For people with chronic low back pain who tolerate the medicine, opioid analgesics provide modest short-term pain relief but the effect is not likely to be clinically important within guideline recommended doses. Evidence on long-term efficacy is lacking. The efficacy of opioid analgesics in acute low back pain is unknown.
Landmark Trial Punctures the Myth That Opioids Provide Powerful Relief of Chronic Pain

BackLetter: July 2017 - Volume 32 - Issue 7 - p 73–81
doi: 10.1097/01.BACK.0000520970.46118.bc

Krebs EE, et al, Effectiveness of opioid therapy vs. non-opioid medication therapy for chronic back & osteoarthritis pain over 12 months. Presented at: the annual meeting, Society for General Internal Medicine, Washington DC, 2017, as yet unpublished.

In the first randomized controlled trial (RCT) with long-term follow-up comparing opioids with non-opioid medications, Erin E. Krebs, MD, and colleagues from the Minneapolis Veterans Health Care System found that opioids provided no better pain relief for patients with low back pain or painful osteoarthritis than safer analgesics such as nonsteroidal anti-inflammatory drugs and acetaminophen—and other nonopioid pain medications.

“Opioids are perceived as strong pain relievers, but our data showed no benefits of opioid therapy over non-opioid medication therapy for pain,” said Krebs in presenting the unpublished study at the 2017 meeting of the Society for General Internal Medicine (SGIM) in Washington, DC. (See Krebs et al., 2017.)

Opioids provided no advantage in terms of function at the 12-month follow-up mark, and patients in the opioid wing of the study actually reported marginally more pain at 12 months than those in the nonopioid group.

“The data do not support opioids' reputation as 'powerful painkillers,’” said Krebs. “The results support CDC [Centers for Disease Control and Prevention] guideline recommendation: that non-opioid medications are preferred for chronic pain.”

They also support the recent recommendation in the American College of Physicians guideline that opioids should be an uncommon treatment—a treatment of last resort—for patients with low back pain.
Comparing Side Effects/Risks

**Acupuncture – “very low risk”**

There were **no unexpected or serious adverse events** associated with this pilot. The most notable adverse event recorded was a single patient who reported a flare of her back pain after an acupuncture session. She subsequently received a prescription muscle relaxant. She said she was in high pain consistent with her typical back pain flares for one week.

Acupuncture has an excellent safety profile. Large, prospective trials have documented that the most common adverse events associated with acupuncture are minor bruising or bleeding.


Comparing Side Effects/Risks

Long term opioid use - “serious risks”

The CDC reports that opioid overdose deaths have quadrupled in the US in the period between 1999 and 2015. Nearly half of these cases involved a prescription opioid.


CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016
https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

“Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy. While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury.”
NSAIDs

NSAID drugs include prescription and over-the-counter drugs such as ibuprofen and naproxen. A systematic review of 17 prospective observational studies found that 11% of preventable drug-related hospital admissions could be attributed to NSAIDs.


Some estimates suggest that each year more than 100,000 patients are hospitalized for NSAID-related GI complications alone, with direct costs ranging from $1800 to $8500 per patient per hospitalization. Moreover, it has been reported that 16,500 persons die annually from these complications. In the elderly, the medical costs of adverse GI events associated with NSAID use likely exceed $4 billion per year.

Professional Guidelines

NIH
National Institutes of Health
Turning Discovery Into Health

National Pain Strategy
A Comprehensive Population Health-Level Strategy for Pain

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

The Joint Commission

FDA

Relieving Pain in America
A Blueprint for Transforming Prevention, Care, Education, and Research
Professional Guidelines

• Institute of Medicine Report and National Pain Strategy – “integrated, interdisciplinary pain assessment and treatment...that includes CAM.”

• 2015 – Joint Commission standard PC.01.02.07 – “both pharmacologic an non-pharmacologic approaches [for pain], as well as benefits and risks to patients” should be considered when determining the most appropriate intervention. Acupuncture mentioned.

• American College of Physicians 2017 – acupuncture and other non-pharmacologic therapies should be used before Tylenol and Advil for the treatment of chronic LBP.
Section 2: Creating the Pain Treatment Plan

II. NONPHARMACOLOGIC THERAPIES

A number of nonpharmacologic therapies are available that can play an important role in managing pain, particularly musculoskeletal pain and chronic pain.

- Psychological approaches – e.g., cognitive behavioral therapy
- Physical rehabilitative approaches – e.g., physical therapy, occupational therapy
- Surgical approaches
- Complementary therapies – e.g., acupuncture, chiropractic
New VT Rule Governing the Prescribing of Opioids for Pain

4.0 Universal Precautions when Prescribing Opioids for Pain

Prior to writing a prescription for an opioid Schedule II, III, or IV Controlled Substance for the first time during a course of treatment to any patient, providers shall adhere to the following universal precautions.

4.1 Consider Non-Opioid and Non-Pharmacological Treatment

Prescribers shall consider non-opioid and non-pharmacological treatments for pain management and include any appropriate treatments in the patient’s medical record. Such treatments may include, but are not limited to:

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- **Acupuncture**
- Osteopathic manipulative treatment
- Chiropractic
- Physical therapy
Insurance Reimbursement
“The Great Wall”
Insurance Reimbursement for acupuncture
What do the experts say?

2011 Institute of Medicine Report “Relieving Pain in America” emphasized “integrated, interdisciplinary pain assessment and treatment that includes complementary and alternative medicine” and recommended that “reimbursement policies should be revised to accommodate this approach.”

2017 National Pain Strategy
Insurance payment policies have been shown to affect consumer choices of treatments, adherence to treatment regimens, and the clinical strategies adopted by health care providers. The structure of payment and coverage arrangements can therefore exert powerful effects on how pain is managed.

... consider acupuncture, cognitive behavioral therapy (CBT) and use of various prescription opioids. Many insurance plans do not cover acupuncture, and if they do provide coverage, subject it to strict duration limits.

Some generic opioids (e.g., methadone) have out-of-pocket costs of as little as $10 to $15 for a 30-day supply. Thus, **consumers in many insurance plans may gravitate to prescription drugs over complementary or alternative treatments, creating risks for subsequent problems with opioid dependency.**
Dr. Madhu Singh, MD – physical medicine and rehab orthopedist:

Many of the complementary and alternative medicine (CAM) therapies aren’t feasible for patients because insurance companies by and large don’t cover them.

“...physicians are often backed into a corner when dealing with a patient’s pain” and default to medications.

“We need to create better access to CAM therapies. By reducing the cost burden on the patient, these therapies become far more accessible.”
Barriers to Access
“Tear down that wall!”

Berlin Wall - 1989
Concluding Thoughts

• The opioid epidemic is multi-causal and acupuncture is not a “silver bullet” that will eradicate this problem.
• The data support acupuncture as a safe and effective approach for chronic pain.
• Acupuncture utilizes a biopsychosocial approach – identified by the National Pain Strategy as ideal for chronic pain.
• Self-care advice is a key component of acupuncture.
• Acupuncture has a better risk/side effect profile than pharmaceuticals commonly used for pain, sleep, and depression.
• Vermont physicians and health pros are willing to refer patients.
• Patients like acupuncture and find it helpful beyond pain control.
• Professional medical guidelines are recommending acupuncture for chronic pain.
• Existing insurance programs spend around $1 per member per month to provide an acupuncture benefit.

BUT
• Patient access to acupuncture is restricted because Medicaid and most Vermont insurances do not cover acupuncture.
This project was supported by an appropriation from the state of Vermont, Agency of Human Services, Department of Health Access

The content is solely the responsibility of the author and does not necessarily represent the views of the Department of Health Access.

Thanks to the team:


- 2015-16 Vermont Senate Health and Welfare Committee
- The Vermont Acupuncture Association and our participating Licensed Acupuncturists.
- 156 Vermonters with chronic pain who participated in our pilot
**Pharmaceutical effect size comparators**

Effect size estimates for treating physical function:

**Opioids for physical function: 0.30 - small effect**
(Placebo and wait list controls)


**Our acupuncture results:**

- **Sleep Disturbance** 23 points (.64 effect size)
- **Fatigue** 19 points (.71 effect size)
- **Pain Interference** 12 points (.61 effect size)
- **Depression** 12 points (.42 effect size)
- **Pain Intensity** 12 points (.35 effect size)
- **Physical Function** 11 points (.44 effect size)
- **Anxiety** 10 points (.40 effect size)
- **Social Isolation** 8 points (.20 effect size)
POPOULATION
VT medicaid enrollees with chronic pain

Inclusion criteria:
• At least 18 years of age
• Qualifying Pain level on a 10-point numeric rating scale for at least 15 out of the past 30 days and for at least the past 3 months.
• Enrolled in Vermont Medicaid
• Able to read and understand English
• Able to understand and sign a consent form

Exclusion criteria:
• Start of a new treatment for pain or any acupuncture treatment within the 4 weeks prior to the onset of treatment in this trial
• Conditions that make treatment difficult: paralysis, psychosis, schizophrenia
• Possible contraindications for acupuncture: pregnancy, uncontrolled seizure or bleeding disorders
INTERVENTION

• Up to 12 treatments by a VT licensed acupuncturist in a 60 day period.
• Treatments administered in Licensed Acupuncturists’ offices.
• No restrictions on how patients were treated, however providers were reimbursed a per visit contracted rate. ($120 - 1st visit, $65 - regular visits)

COMPARISON

• Pre- and post-test measurements
• No control group
OUTCOMES

• Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaires
  • Developed and validated by NIH to be relevant across all conditions to assess symptoms and functions
  • Pain intensity, pain interference, fatigue, anxiety, depression, sleep disturbance, physical function, social isolation

• Open-ended questionnaire
  • Medication use, occupational status

• DVHA utilization analyses
  • Use of other medical resources – ER, PCP, prescriptions, other health care visits
  • 60 days prior, during, and after treatment

• Descriptive data – total visits used, main complaints, co-morbidities, modalities, referrals, etc
Pain Intensity – Short Form 3a

Please respond to each item by marking one box per row.

In the past 7 days...

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Had no pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mild</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Severe</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Very severe</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PAINQU6

How intense was your pain at its worst?....

1

PAINQU8

How intense was your average pain?..........  

1 2 3 4

PAINQu21

What is your level of pain right now?........

1 2 3 4 5
## OUTCOMES – PROMIS  Pain Interference Short Form 8a

In the past 7 days...

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much did pain interfere with your day to day activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with work around the home?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with your ability to participate in social activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with your household chores?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with the things you usually do for fun?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with your enjoyment of social activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with your enjoyment of life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How much did pain interfere with your family life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
## OUTCOMES - PROMIS Fatigue Short Form 8a

### During the past 7 days...

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel fatigued</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>AN3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have trouble starting things because I am tired</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### In the past 7 days...

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>FATEXP41</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How run-down did you feel on average? ...</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>FATEXP40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How fatigued were you on average? ........</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
# OUTCOMES - PROMIS Fatigue Anxiety and Depression Short Forms 4a

## In the past 7 days...

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I felt fearful</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I found it hard to focus on anything other than my anxiety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My worries overwhelmed me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt uneasy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt worthless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt helpless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt depressed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt hopeless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

B12
### OUTCOMES - PROMIS

Sleep Disturbance 4a and Social Isolation 4a

#### In the past 7 days...

<table>
<thead>
<tr>
<th>Sleep109</th>
<th>Very poor</th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
<tbody>
<tr>
<td>My sleep quality was</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sleep116</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>My sleep was refreshing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

| Sleep20                   |           |               |           |              |           |
| I had a problem with my sleep |          |               |           |              |           |
|                           | 1         | 2             | 3         | 4            | 5         |

| Sleep44                   |           |               |           |              |           |
| I had difficulty falling asleep |          |               |           |              |           |
|                           | 1         | 2             | 3         | 4            | 5         |

<table>
<thead>
<tr>
<th>UCLA11x2</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel left out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

| UCLA13x3                  |           |               |           |              |           |
| I feel that people barely know me |          |               |           |              |           |
|                           | 1         | 2             | 3         | 4            | 5         |

| UCLA14x2                  |           |               |           |              |           |
| I feel isolated from others |          |               |           |              |           |
|                           | 1         | 2             | 3         | 4            | 5         |

<p>| UCLA18x2                  |           |               |           |              |           |
| I feel that people are around me but not with me |          |               |           |              |           |
|                           | 1         | 2             | 3         | 4            | 5         |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Without any difficulty</th>
<th>With a little difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Unable to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you able to do chores such as vacuuming or yard work?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA11</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Are you able to go up and down stairs at a normal pace?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA21</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Are you able to go for a walk of at least 15 minutes?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA23</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Are you able to run errands and shop?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA50</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Does your health now limit you in doing two hours of physical labor?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFC12</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFB1</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Does your health now limit you in lifting or carrying groceries?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA5</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFA4</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
Acupuncture needle vs. hypodermic needle