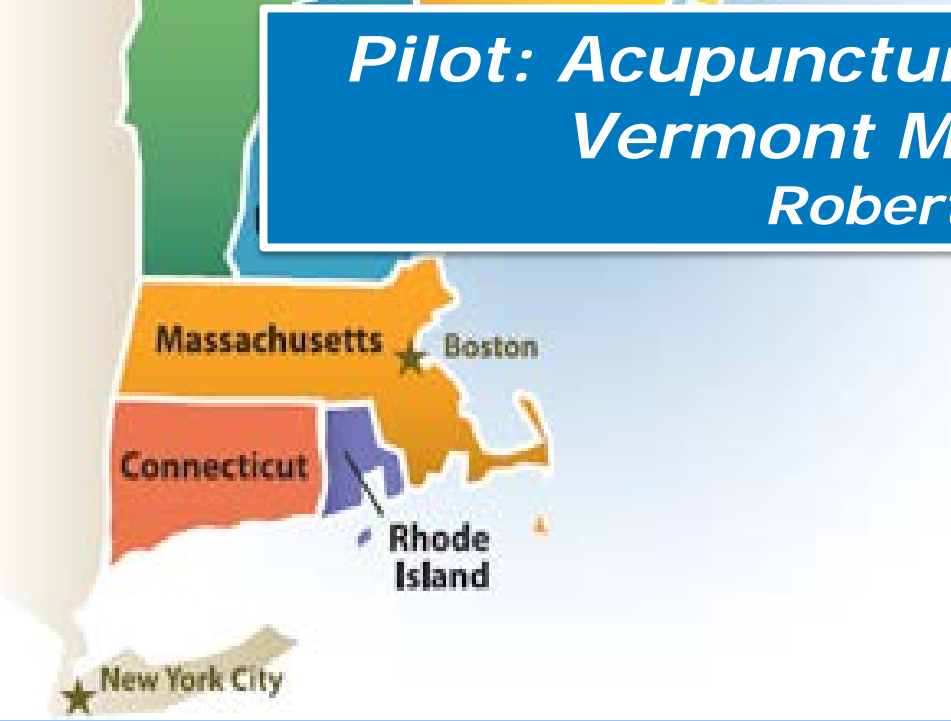
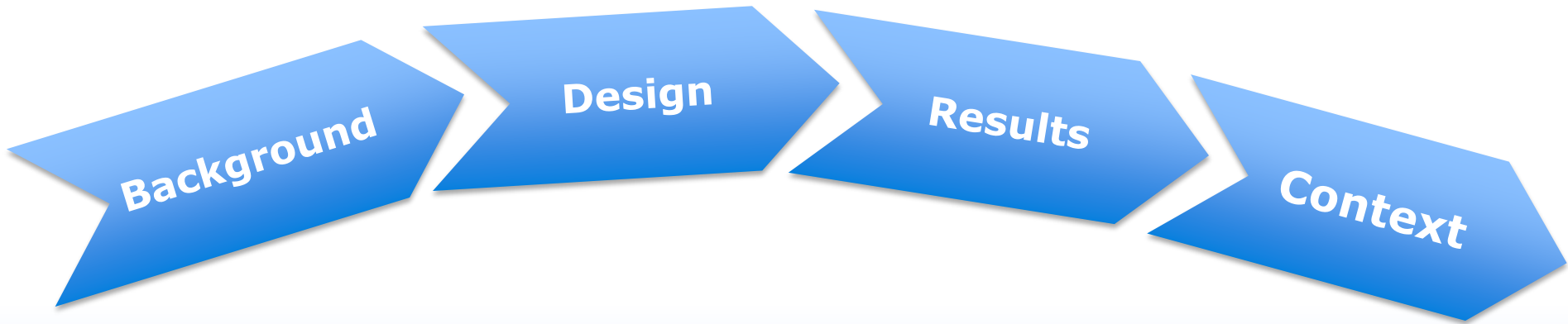




***Pilot: Acupuncture for Chronic Pain in the Vermont Medicaid Population***  
***Robert Davis, MS, LAc***



# Overview of Presentation



# *VT Senate Committee on Health and Welfare 2015-16 Session*



Ayer



Lyons



Pollina



Collamore



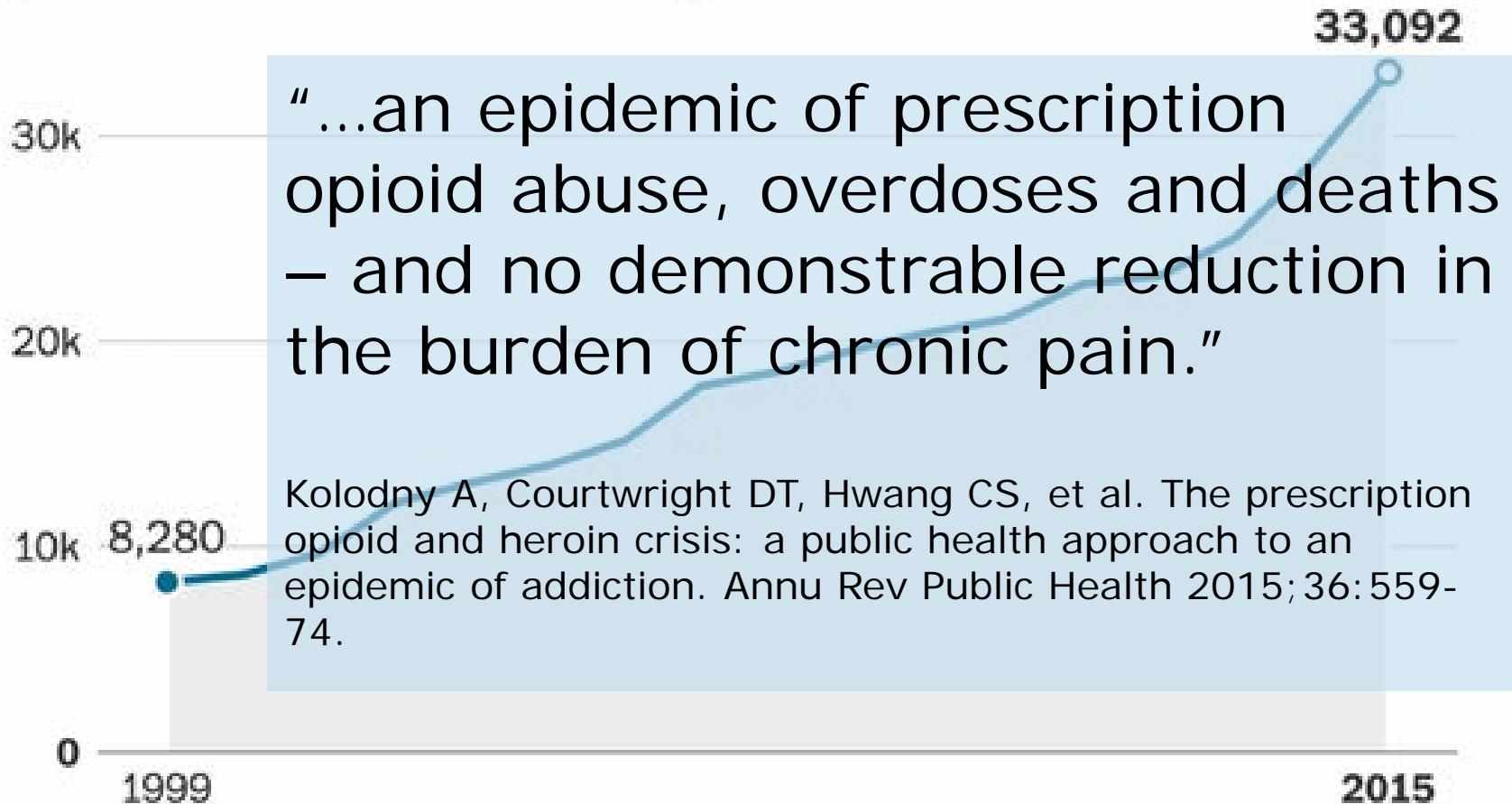
McCormack

**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

## Opioid overdose deaths surge in 2015

- > deaths at height of AIDS epidemic
- > deaths by traffic fatalities

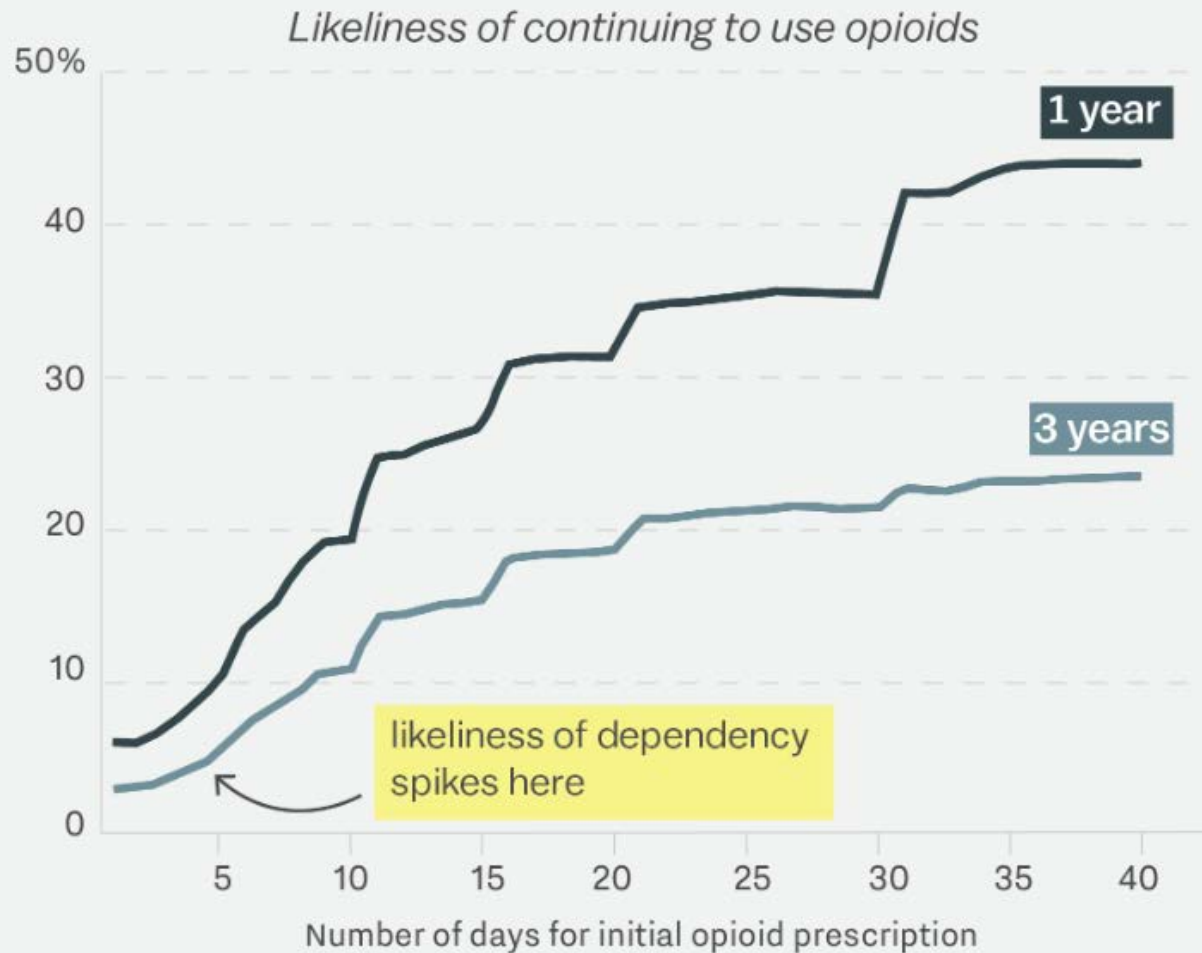


"...an epidemic of prescription opioid abuse, overdoses and deaths – and no demonstrable reduction in the burden of chronic pain."

Kolodny A, Courtwright DT, Hwang CS, et al. The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health* 2015; 36:559-74.

# Opioid Crisis - How did we get here?

## Risk of continued opioid use increases at 4-5 days



Source: Centers for Disease Control and Prevention

Credit: Sarah Frostenson

**Vox**

# *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. N ENGL J MED 373;22 NEJM.ORG NOVEMBER 26, 2015

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

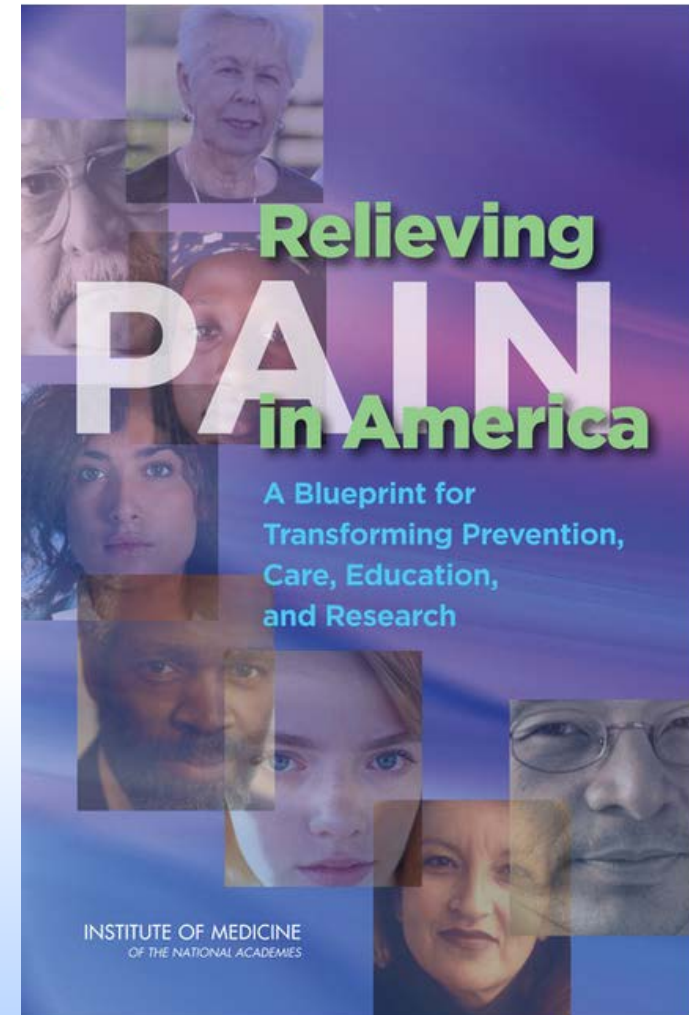
# Opioid Crisis - Where do we go now?



## 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

MacPherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34,000 treatments by traditional acupuncturists. *BMJ* 2001;323:486-7.

Melchart D, Weidenhammer W, Streng A, et al. Prospective investigation of adverse effects of acupuncture in 97,733 patients. *Arch Intern Med* 2004;164:104-5.

Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed* 2009;16:91-7.



# Acupuncture is Effective for Chronic Pain

## Acupuncture for Chronic Pain

Individual Patient Data Meta-analysis

17,922 patients analyzed

Andrew J. Vickers, DPhil; Angel M. Cronin, MS; Alexandra C. Maschino, BS; George Lewith, MD; Hugh MacPherson, PhD; Nadine E. Foster, DPhil; Karen J. Sherman, PhD; Claudia M. Witt, MD; Klaus Linde, MD; for the Acupuncture Trialists' Collaboration

.... "significant difference between true and sham acupuncture indicate that acupuncture is more than a placebo"

**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.

(95% CI, 0.13-0.33), 0.16 (95% CI, 0.07-0.25), and 0.15 (95% CI, 0.07-0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively; the effect sizes in comparison to no-acupuncture controls were 0.55 (95% CI, 0.51-0.58), 0.57 (95% CI, 0.50-0.64), and 0.42 (95% CI, 0.37-0.46) SDs. These results were robust to a variety of sensitivity analyses, including those related to publication bias.

**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.

Arch Intern Med.  
Published online September 10, 2012.  
doi:10.1001/archinternmed.2012.3654

.... "Acupuncture is effective for the treatment of chronic pain"

acupuncture had less pain, with scores that were 0.23

# 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.

<sup>a</sup> Department  
<sup>b</sup> Foundation  
<sup>c</sup> School of H  
Available on

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

KEYWORD  
Self-help  
Acupuncture;  
Low back pain;

acupunctu  
ponents. h

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

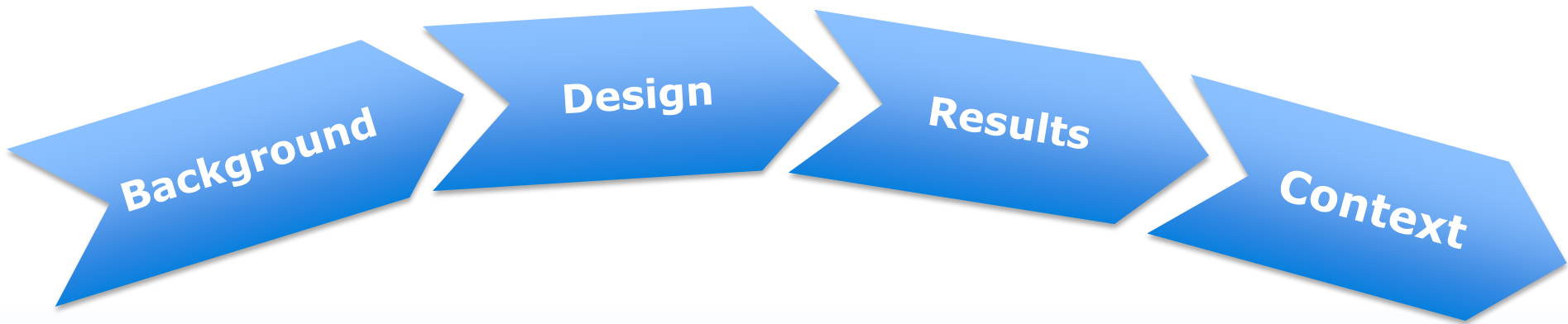
treatment

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.

Design Data for this study were assembled from five randomized trials evaluating six different CAM treatments for back pain. A conventional qualitative content analysis was conducted on responses to open-ended questions asked at the end of telephone interviews assessing treatment outcomes.

**Subjects:** A total of 884 study participants who received CAM therapies completed post-treatment interviews. Of these, 327 provided qualitative data used in the analyses.

# Overview of Presentation



# 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



State of Vermont  
Department of Vermont Health Access [Phone] 802-879-5900  
280 State Street, NOB 1 South  
Waterbury, VT 05671-1010  
<http://dvha.vermont.gov>

Agency of Human Services

### MEMORANDUM

**To:** House Committees on Health Care and on Human Services; Senate Committee on Health and Welfare

**From:** Cory Gustafson, Commissioner, Department of Vermont Health Access

**CC:** Al Gobeille, Secretary, Agency of Human Services

**Date:** January 13, 2017

**Re:** Act 173, Sec. 15a – Acupuncture Pilot Project Progress Report

This memorandum is in response to the legislature's request in Act 173, Section 15a, that the Department of Vermont Health Access (DVHA) provide a progress report on the acupuncture pilot project that includes an implementation plan for the pilot project described in this section.

#### Acupuncture for Chronic Pain in the Vermont Medicaid Population Progress Report for the Legislature

**Purpose and Funding:** In seeking to address issues related to the opioid crisis, Vermont legislators noted that non-pharmacologic treatments have been recognized as an important strategy in the management of pain.<sup>1,2</sup> An advantage of this approach is the avoidance of serious adverse events.<sup>3-5</sup> The efficacy of acupuncture for the treatment of many common chronic pain

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE  
Volume 23, Number 7, 2017, pp. 499-501  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/acm.2017.29032.rjd



#### SAR TURNING POINTS



### Vermont Policy Makers Assess the Effectiveness of Acupuncture Treatment for Chronic Pain in Medicaid Enrollees

Robert Davis, MS, LAc

**Editor's Note:** For many years, *JACM* has been proud to be the official journal of the influential Society for Acupuncture Research. Since the change in *JACM* editorial leadership last year, we have begun exploring ways to make this relationship of highest value to both parties, and to the researchers, clinicians, educators, and policy makers we serve. With this issue, we initiate a quarterly column from Society for Acupuncture Research (SAR) leadership, *Turning Points*. Each column will engage a transformational topic relative to paradigm, practice, and policy in the acupuncture research community. This first, from SAR copresident Robert Davis, MS, LAc, shares the research strategy a SAR team developed for a high visibility pilot project in the United States. The question: with a limited budget and a tight time frame, how best to explore acupuncture for chronic pain in an underserved population that does not typically have access to acupuncture services? A fine starting place for what we hope will enrich your *JACM* experience! —John Weeks, Editor-in-Chief, *JACM*.

**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**

**Pragmatic**

**standardized**

**Treatment**

**Close to usual care**

**homogenous**

**Patients**

**heterogeneous**

**objective**

**Outcomes**

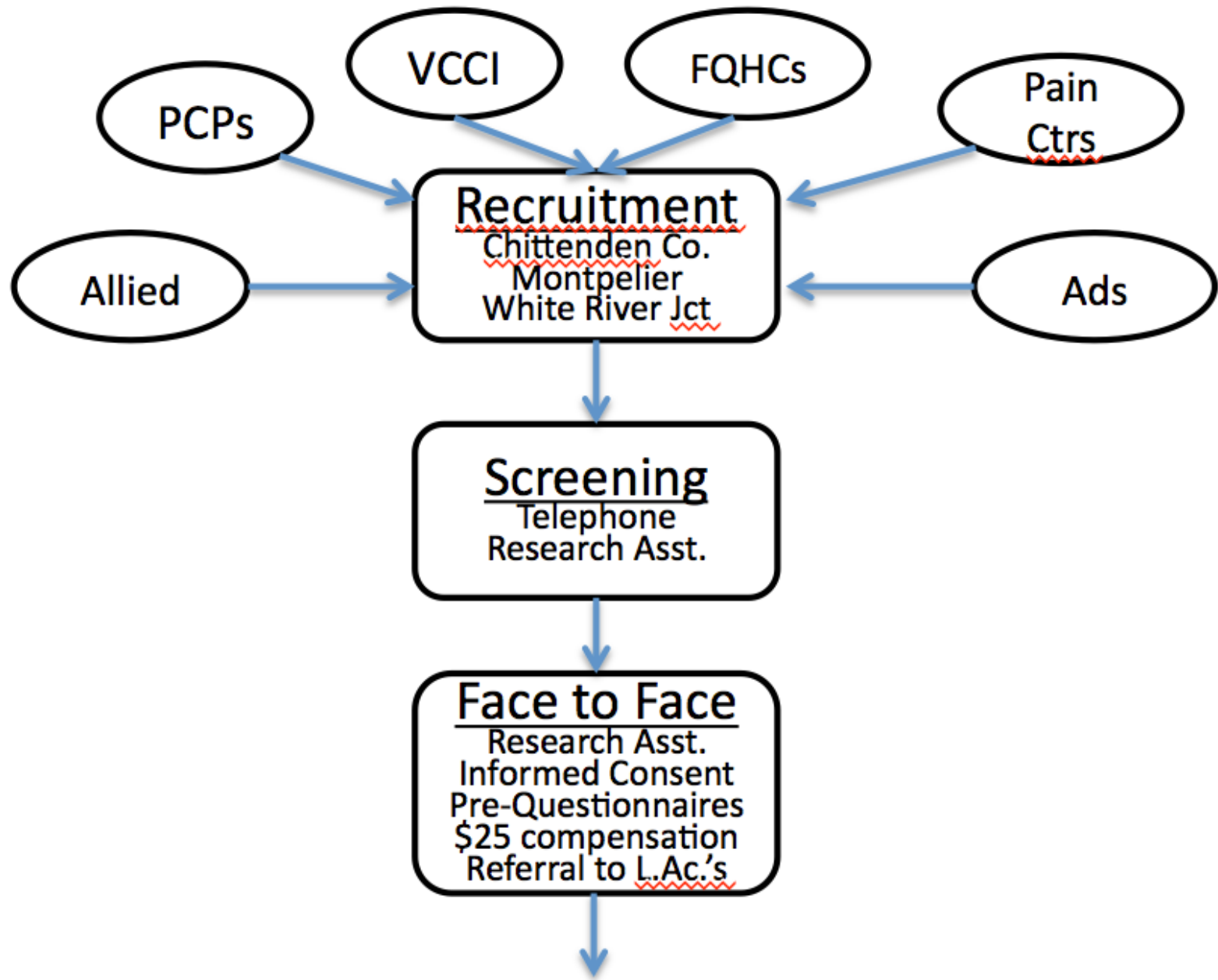
**Patient centered**

**Internal ↑**

**Validity**

**External ↑**

# Acupuncture for Chronic Pain in the Vermont Medicaid Population





```
graph TD; A[Treatments] --> B[Face to Face]; B --> C[Assessment];
```

## 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

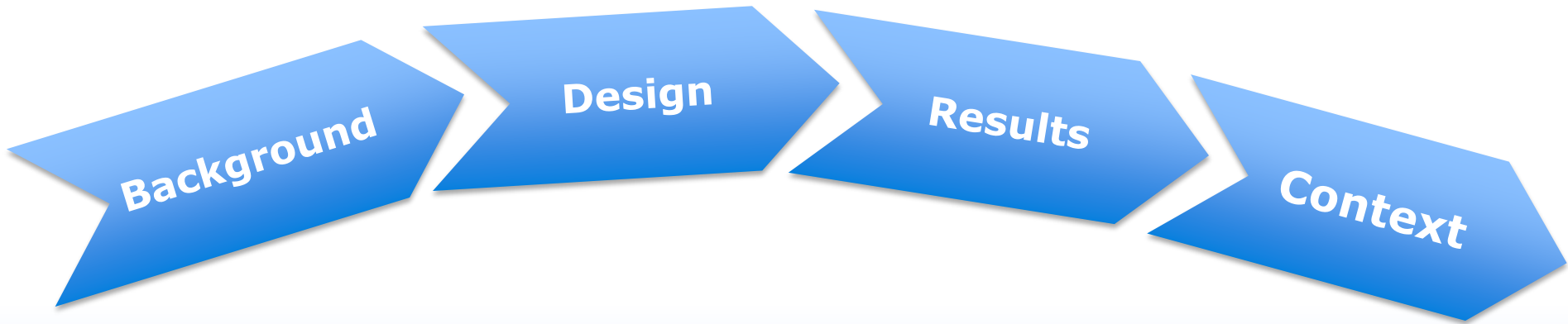
## Face to Face

Research Asst.  
Post-Questionnaires  
\$25 compensation

## Assessment

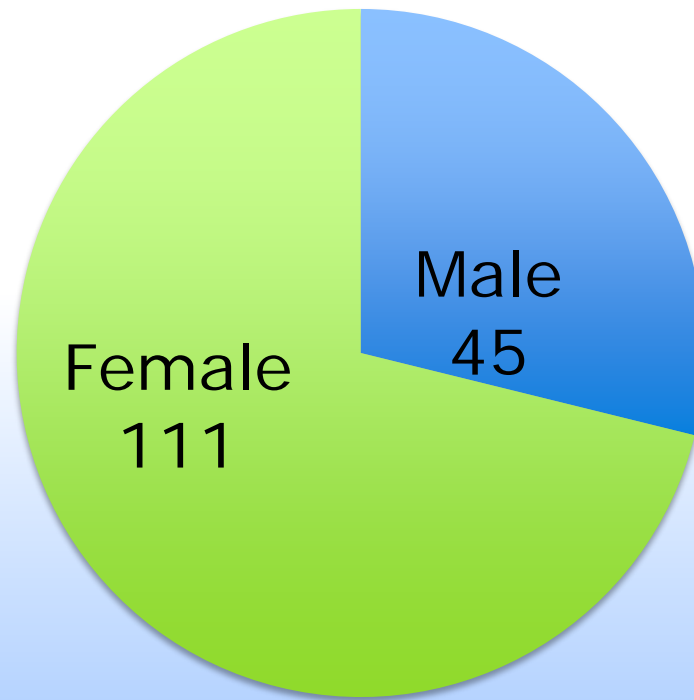
Pre-Post Change  
Utilization Review(60/60/60)  
Descriptive data

# Overview of Presentation



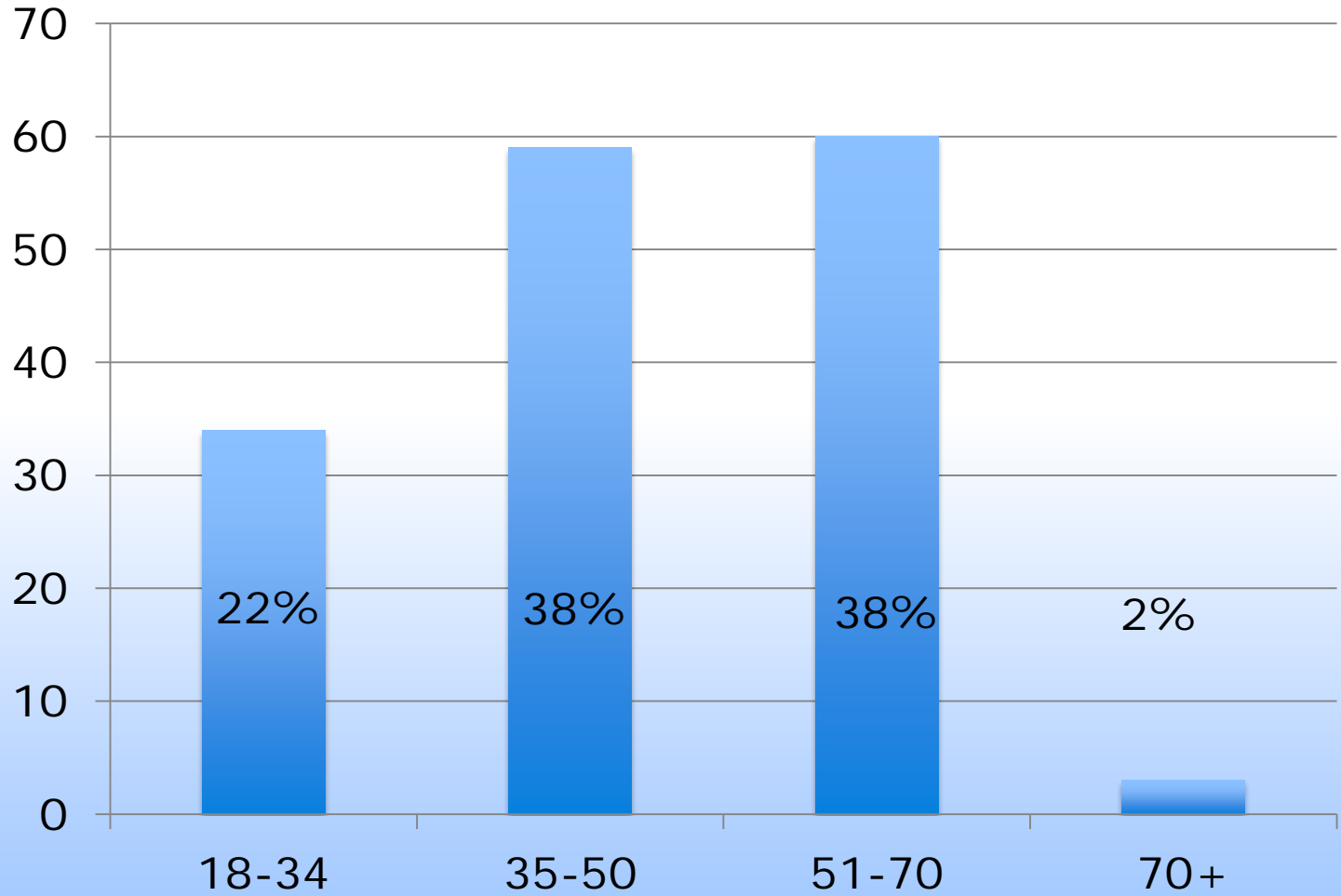
# *Descriptive Statistics: Patients*

156 Total Patients entered pilot  
29% males, 71% females



# *Descriptive Statistics: Patients*

## Distribution by Age



# *Descriptive Statistics: distribution by region*

Chittenden County

15 acupuncturists, 578 treatments

Washington County

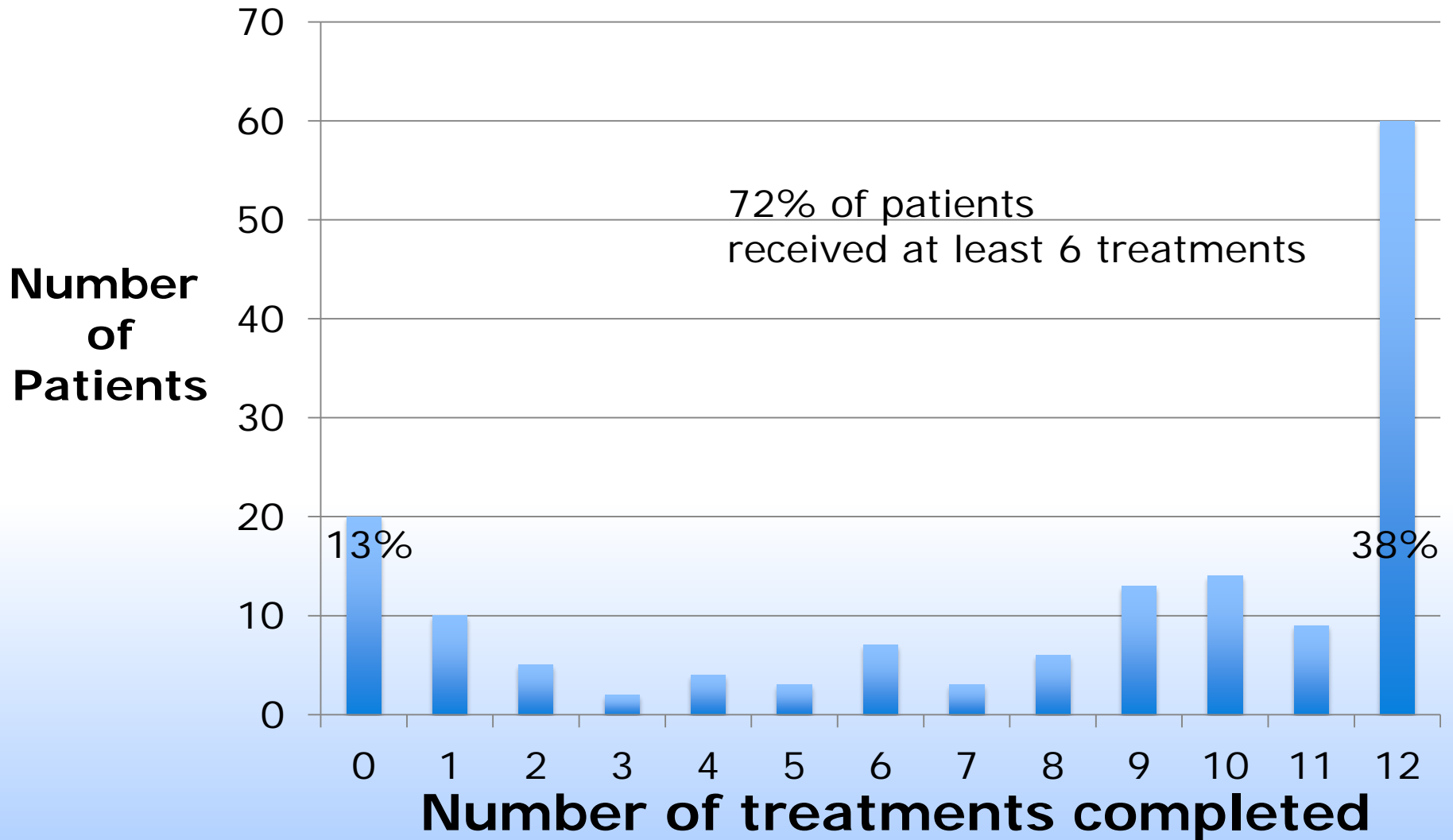
10 acupuncturists, 595 treatments

Windsor County

3 acupuncturists, 101 treatments

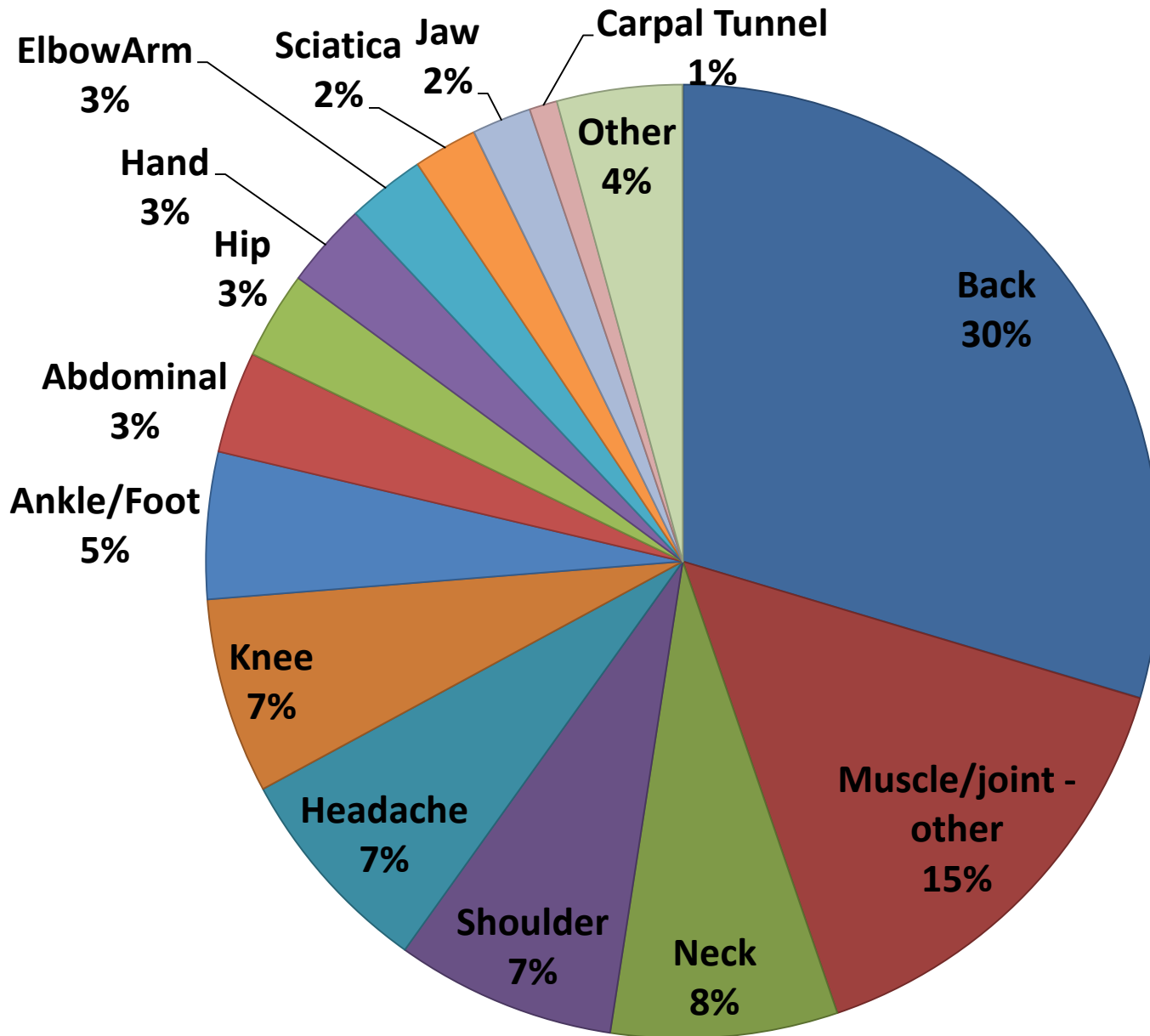
Total = 1274 treatments by 28 Licensed  
Acupuncturists in three regions of Vermont

# Descriptive Statistics



No significant differences were detected between baseline outcome measures and patients who received or did not receive treatments.

# Participant Chief Pain Complaints



# *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:

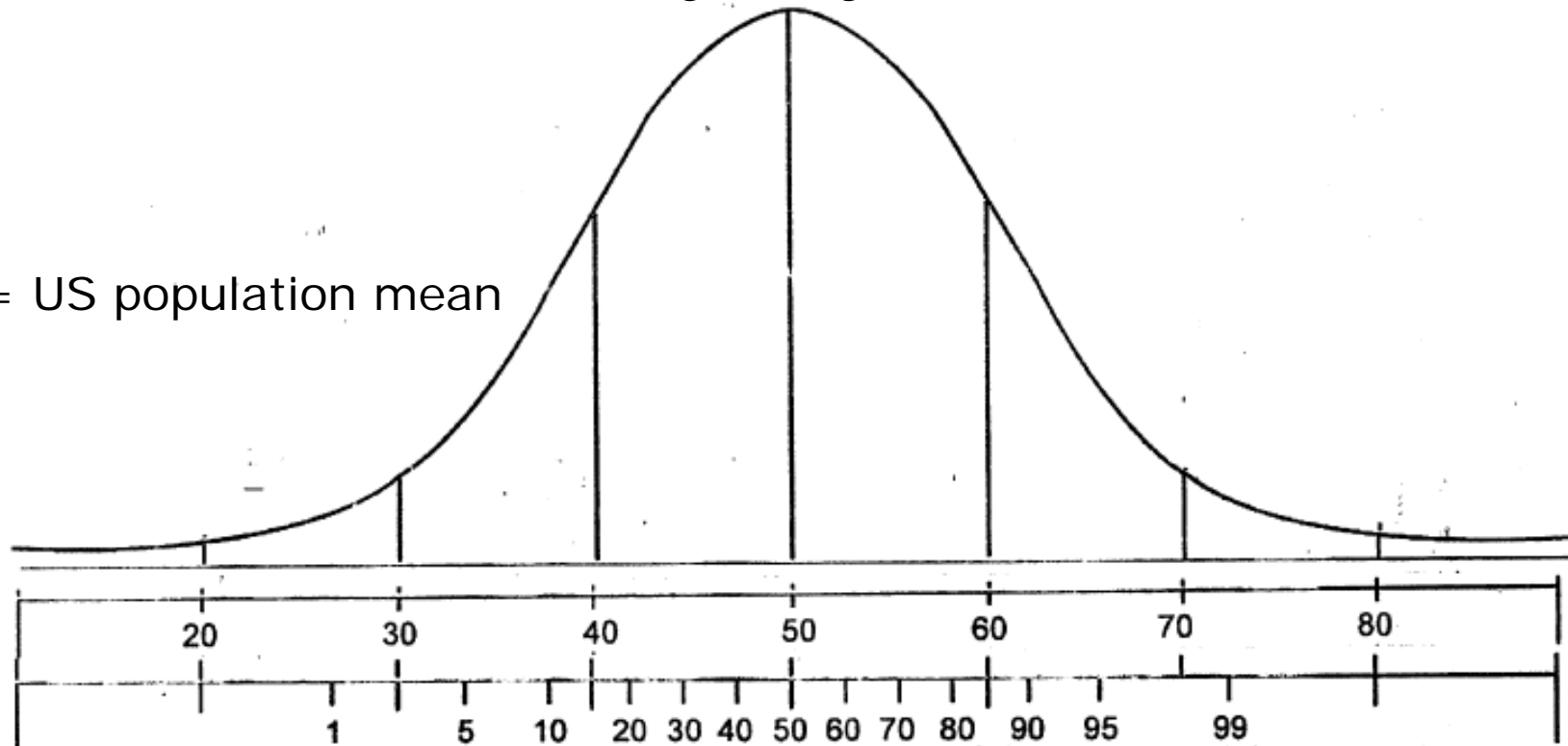
## Three Important Points of Reference

### 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.***

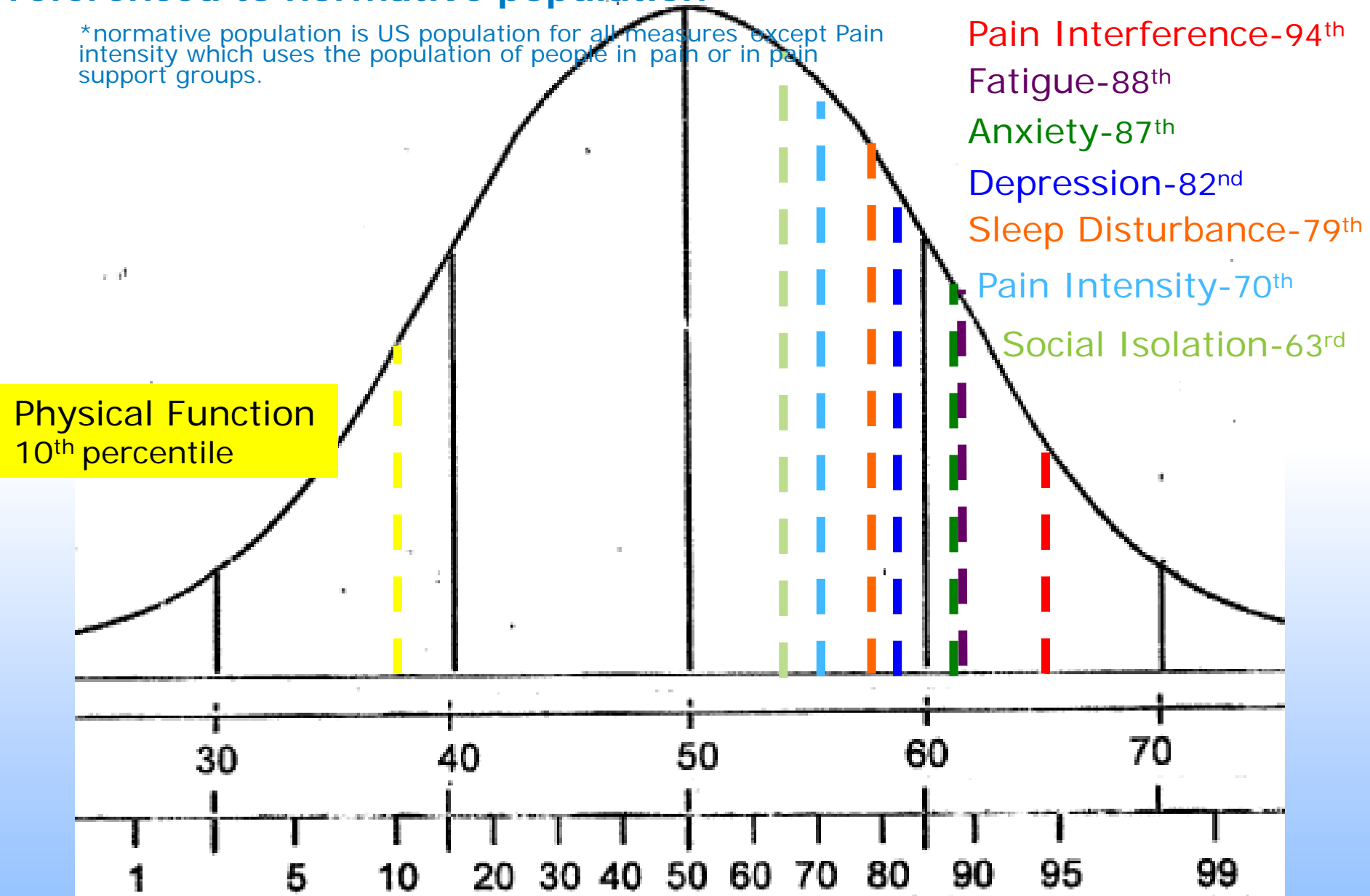
50 = US population mean



# 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.



Physical Function  
10<sup>th</sup> percentile

# RESULTS:

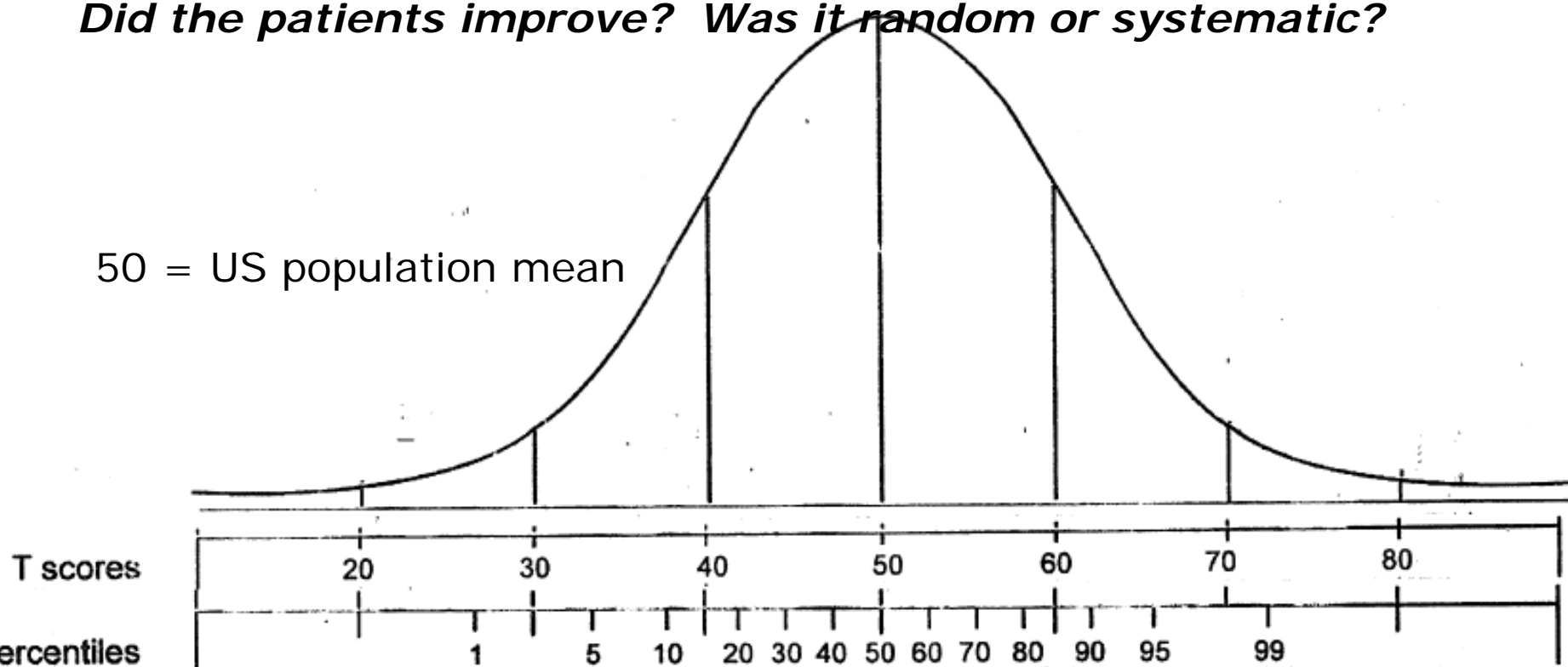
## Three Important Points of Reference

### 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)

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

**Fatigue** 88<sup>th</sup> to 69<sup>th</sup>  
ES .71 Paired T-test p<0.01

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

**Depression** 82<sup>nd</sup> to 70<sup>th</sup>  
ES .42 Paired T-test

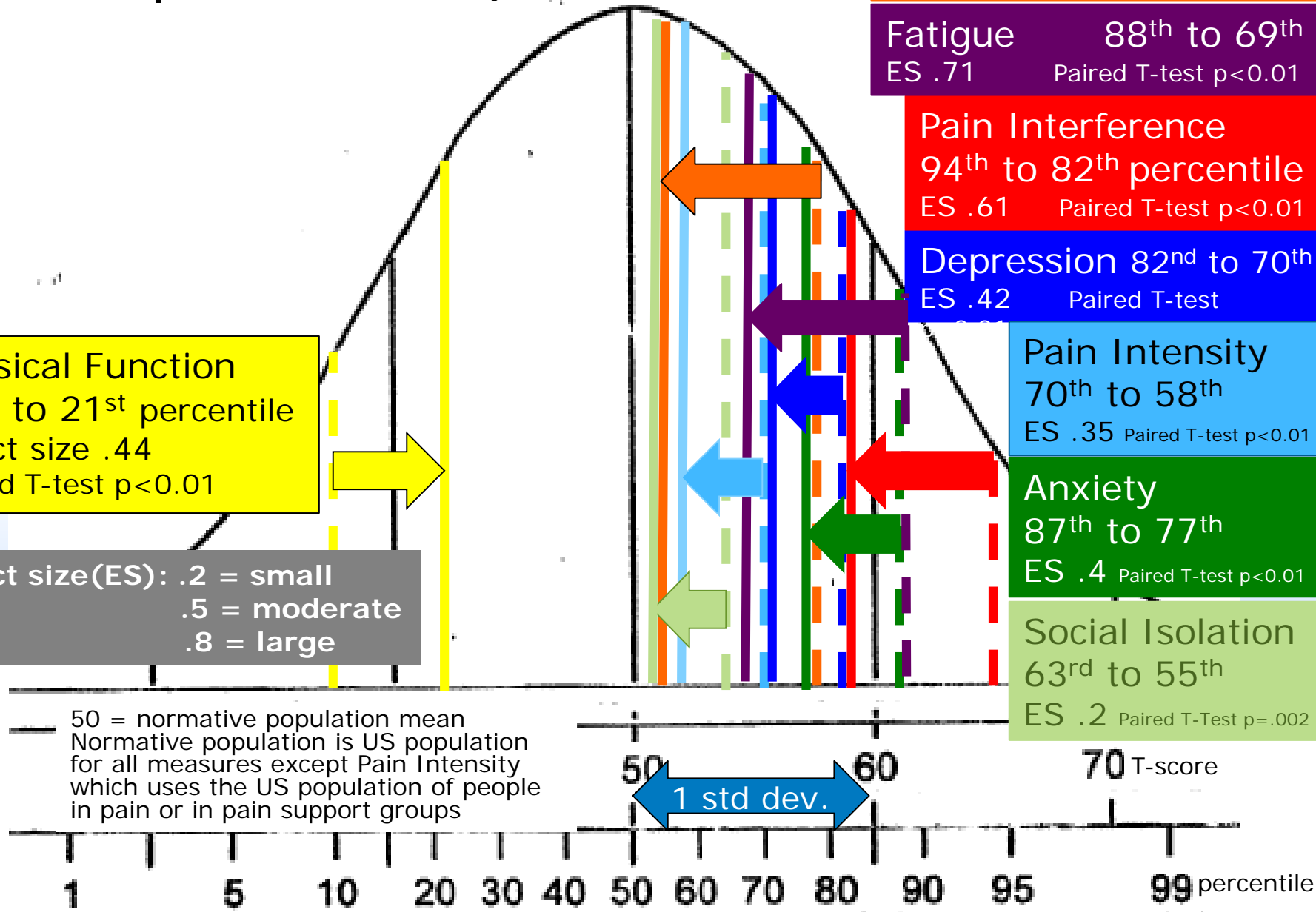
**Pain Intensity**  
70<sup>th</sup> to 58<sup>th</sup>  
ES .35 Paired T-test p<0.01

**Anxiety**  
87<sup>th</sup> to 77<sup>th</sup>  
ES .4 Paired T-test p<0.01

**Social Isolation**  
63<sup>rd</sup> to 55<sup>th</sup>  
ES .2 Paired T-Test p=.002

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

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



# **RESULTS:**

## ***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.

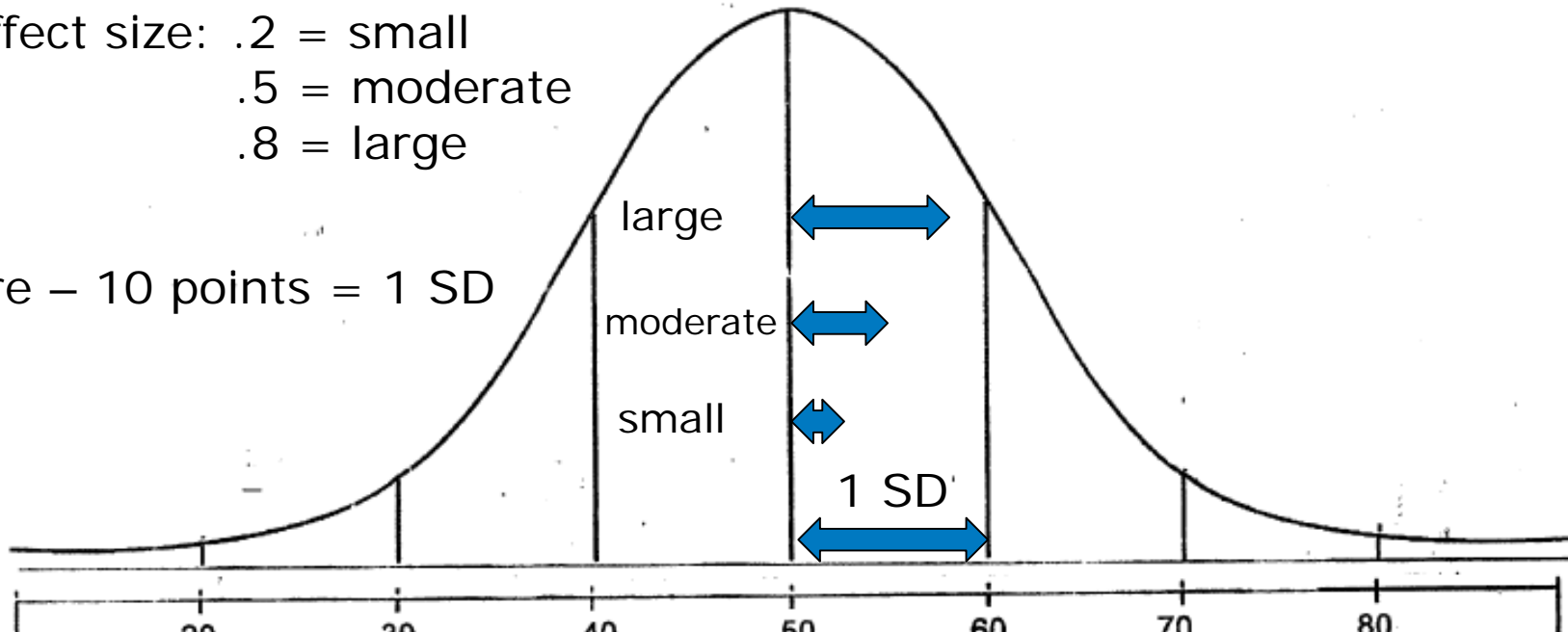
#### standardized metrics of effect size

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?

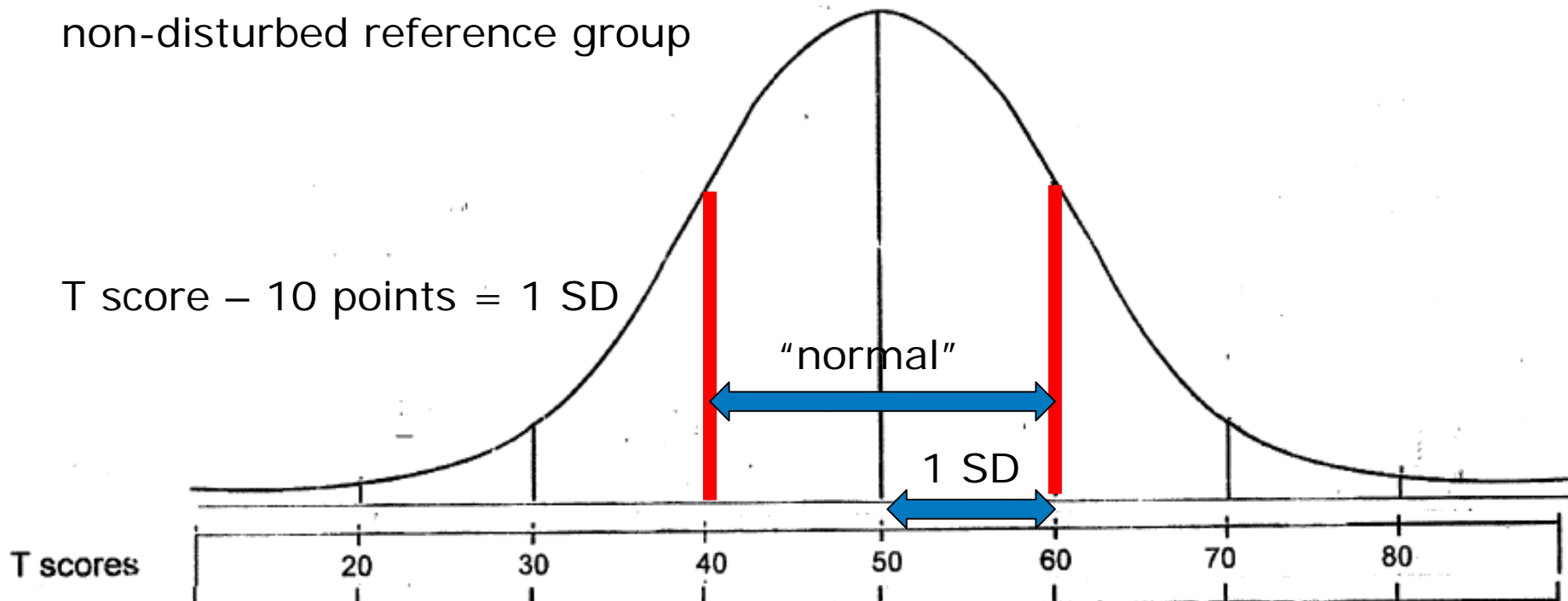
By comparing our observed changes against:

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



# Change in PROMIS scores (pre vs. post-treatment)

**Sleep Disturbance**  
79<sup>th</sup> to 56<sup>th</sup> percentile  
ES .64 Paired T-test  $p < 0.01$

**Fatigue** 88<sup>th</sup> to 69<sup>th</sup>  
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**Pain Interference**  
94<sup>th</sup> to 82<sup>th</sup> percentile  
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ES .42 Paired T-test

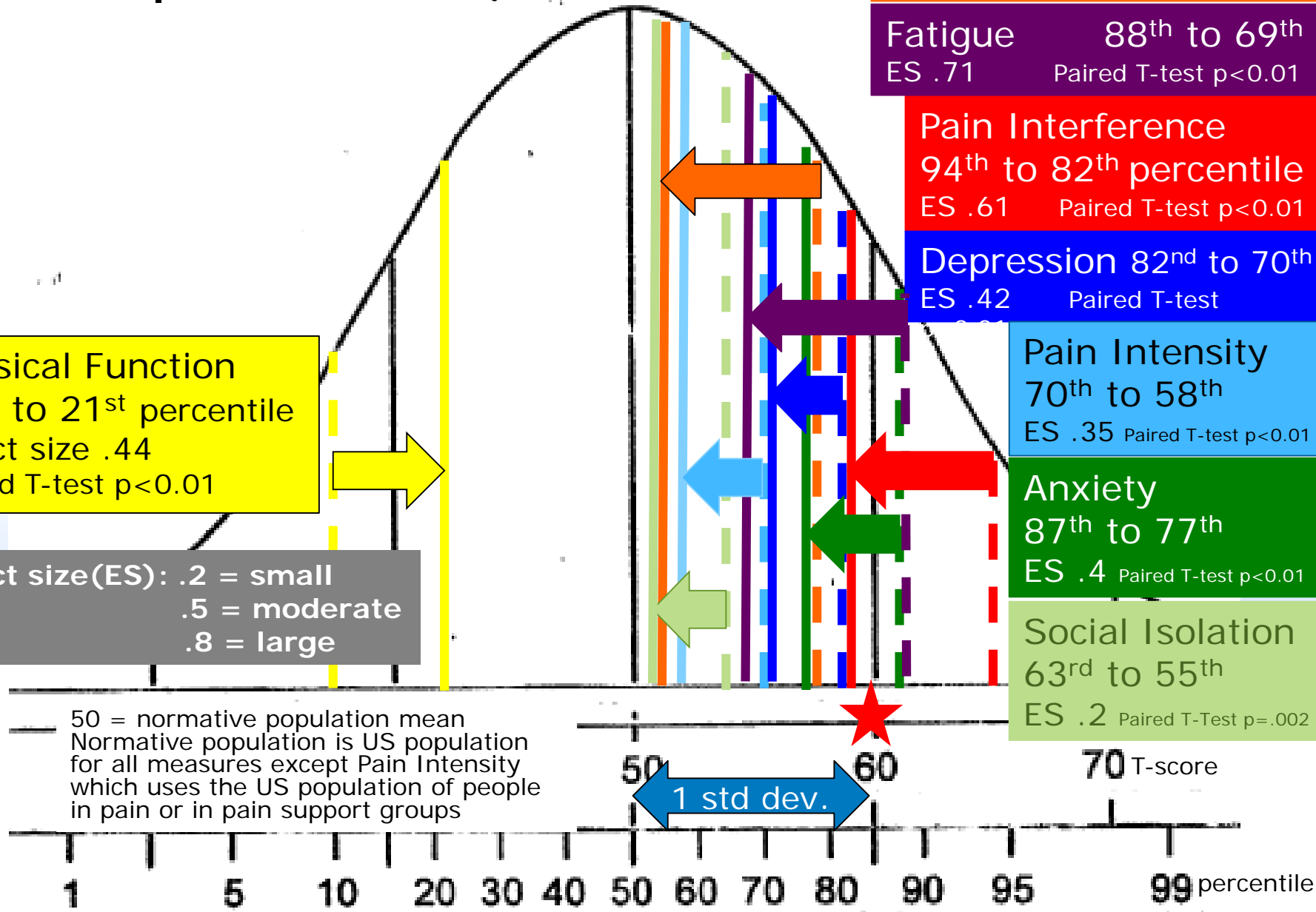
**Pain Intensity**  
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10<sup>th</sup> to 21<sup>st</sup> percentile  
Effect size .44  
Paired T-test  $p < 0.01$

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





# 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

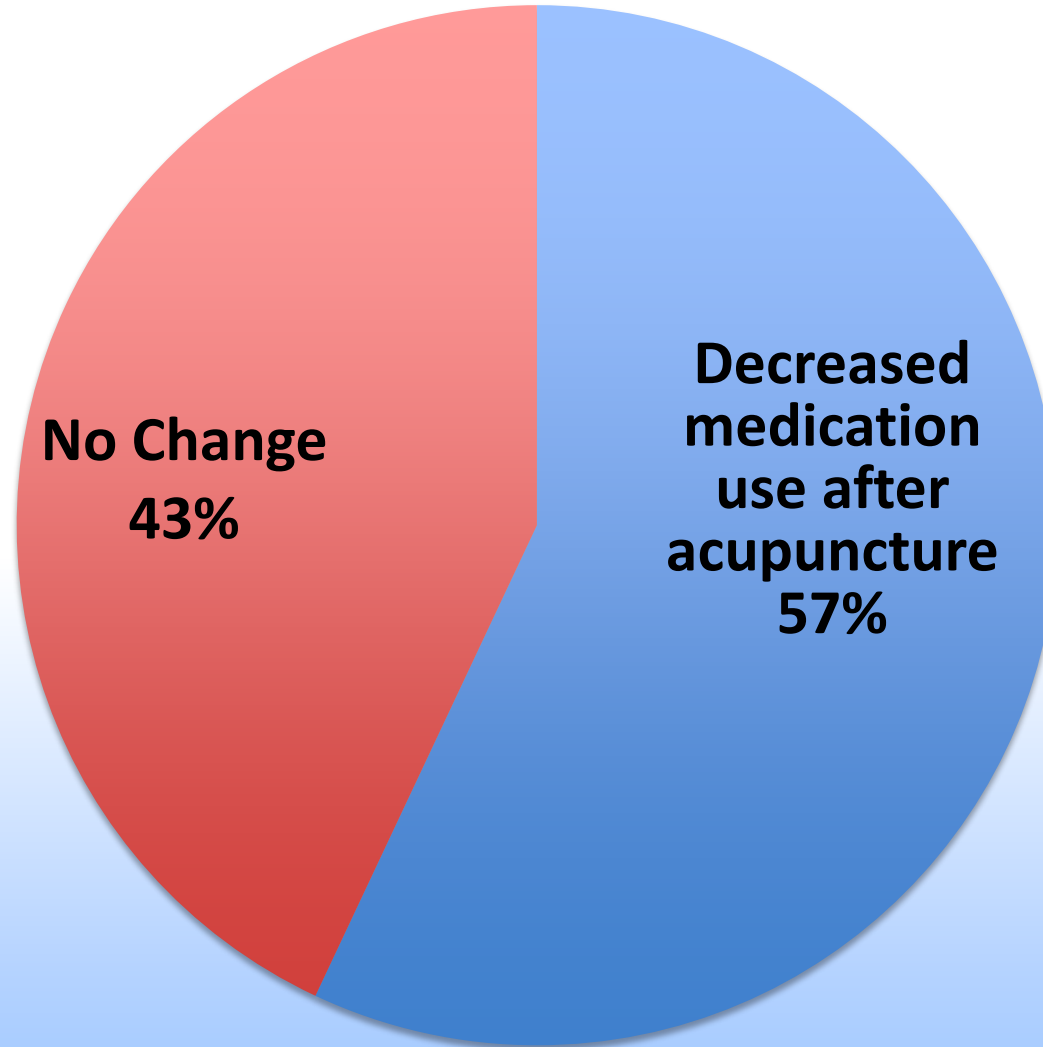
## Post-intervention questionnaire

- 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.

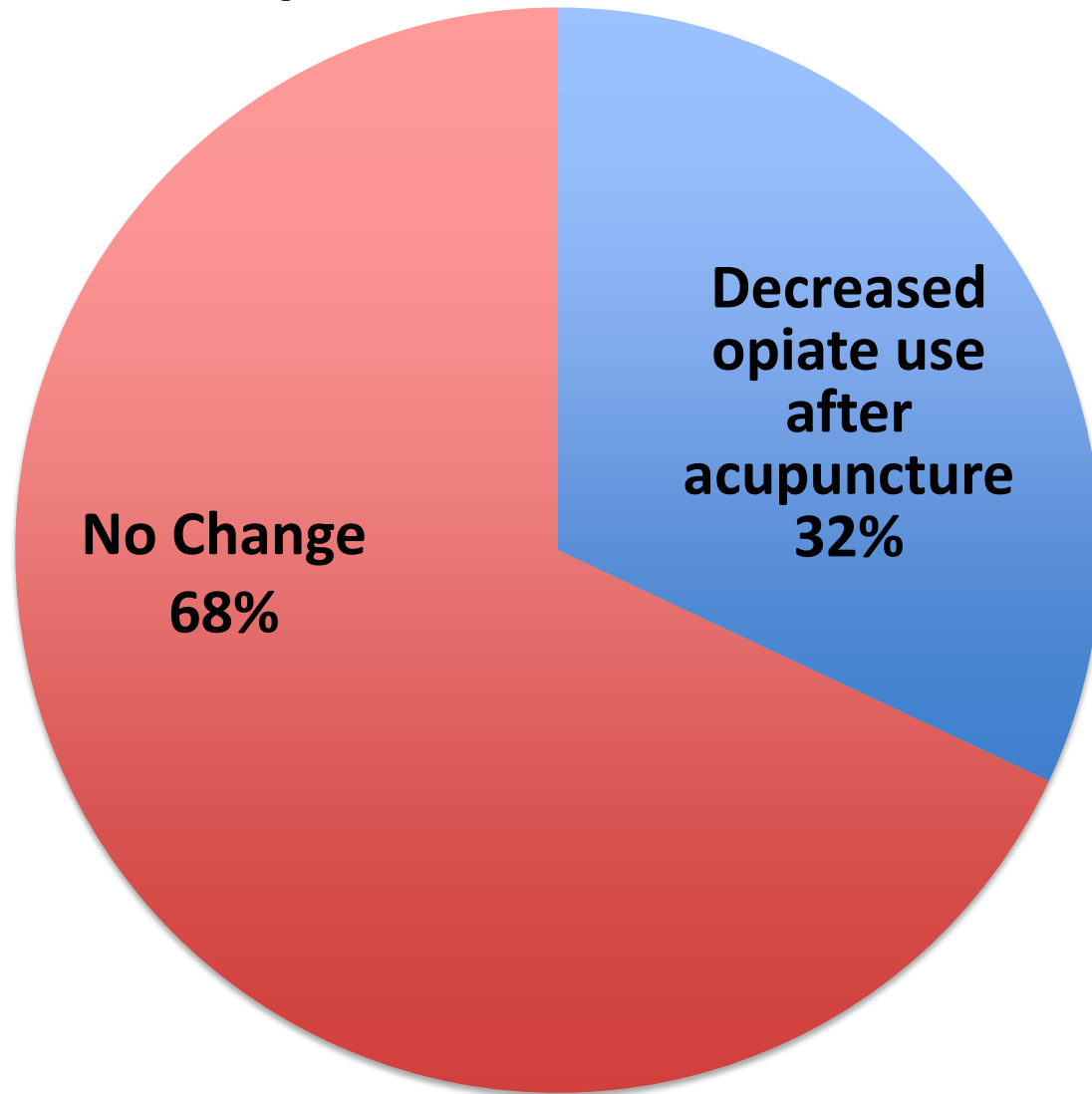
# *Self Reported Medication Use*

43% of those using medications experienced unwanted side effects including “upset stomach, nausea, drowsiness, constipation, fatigue, dry mouth, grogginess, lightheadedness, forgetfulness.”

## Medication Users (N=82)



## Opiate Users (N=47)



# *Self Reported Medication Use*

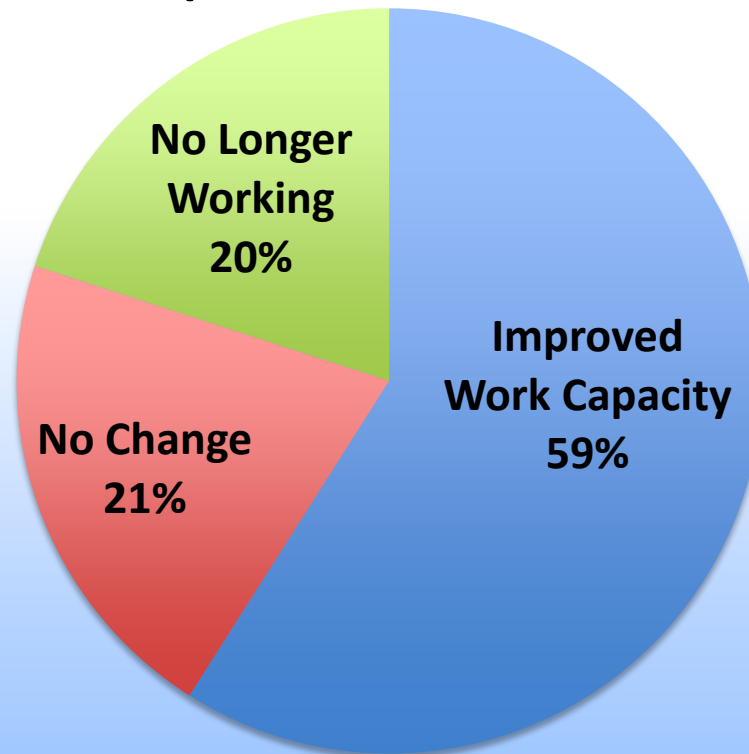
## **Sample Quotes – medication use**

- “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”

# *Self Reported Work Status*

**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)**



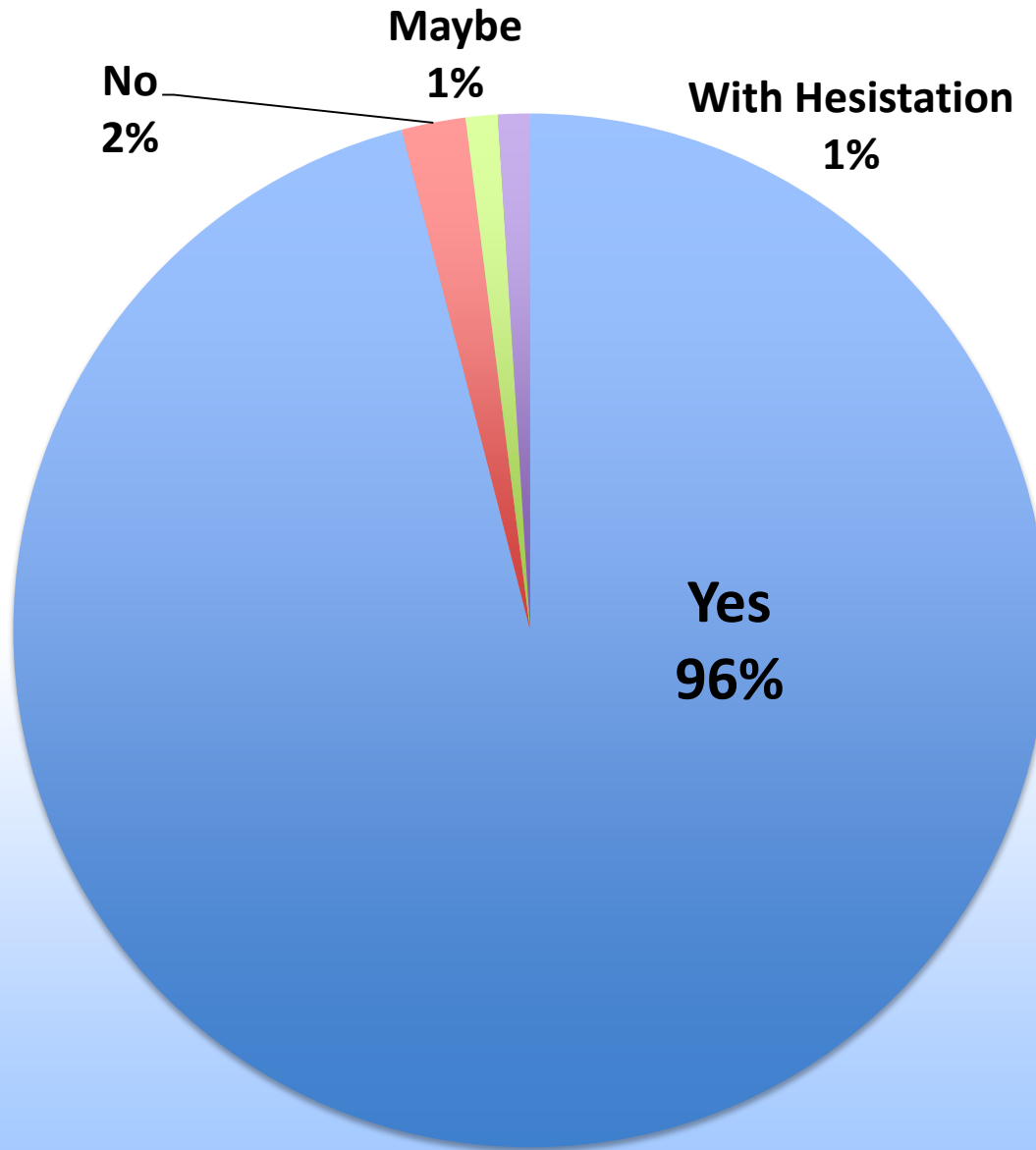
# ***Results: Self Reported Work Status***

## **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"



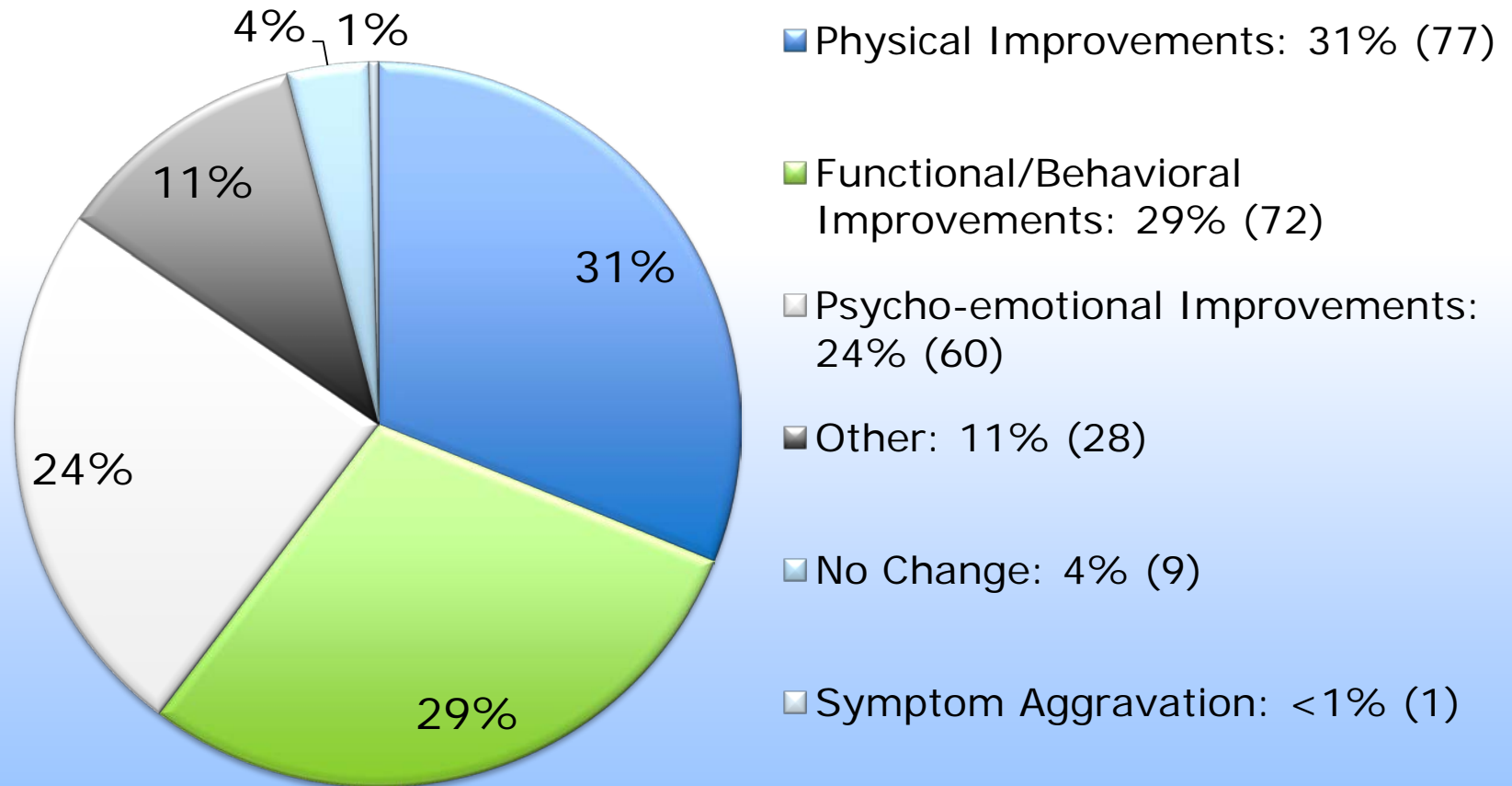
# Would you recommend acupuncture to someone else with chronic pain?



# “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



# *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."

# *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."



# 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."



# *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)

Longer term follow up data from  
20 trials, 6376 patients

Pain. 2017 May;158(5):784-793. doi: 10.1097/j.pain.0000000000000747.

## The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of patients with chronic pain.

MacPherson H<sup>1</sup>, Vertosick EA, Foster NE, Lewith G, Linde K, Sherman KJ, Witt CM, Vickers AJ.

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

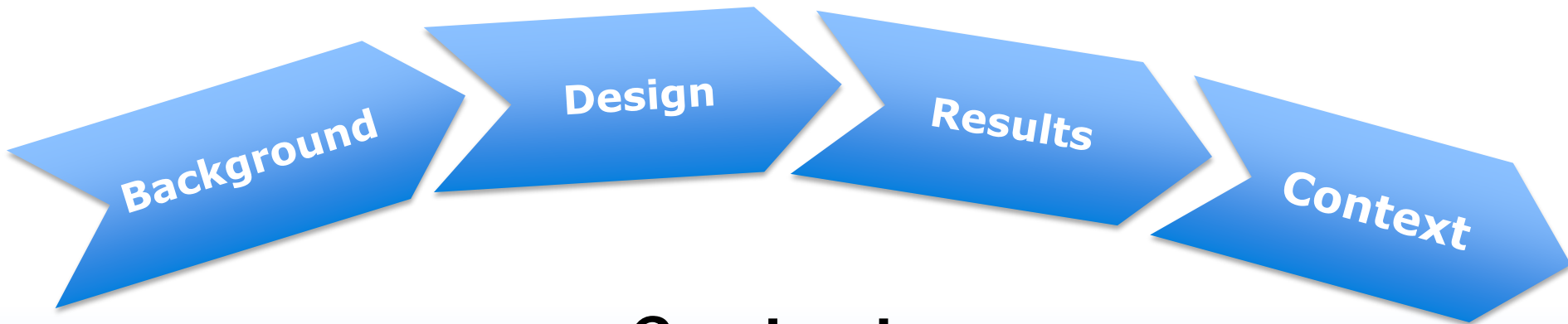
“...suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months.”

...nonsignificant 0.011 SD per 3 months (95% confidence interval: -0.014 to 0.037, P = 0.4) after treatment ended. The central estimate suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months. For trials comparing acupuncture to sham, we observed a reduction in effect size of 0.025 SD per 3 months (95% confidence interval: 0.000-0.050, P = 0.050), suggesting approximately a 50% diminution at 12 months. The effects of a course of acupuncture treatment for patients with chronic pain do not seem to decrease importantly over 12 months. Patients can generally be reassured that treatment effects persist. Studies of the cost-effectiveness of acupuncture should take our findings into account when considering the time horizon of acupuncture effects. Further research should measure longer term outcomes of acupuncture.

PMID: 27764035 PMCID: [PMC5393924](https://pubmed.ncbi.nlm.nih.gov/PMC5393924/) [Available on 2018-05-01] DOI: [10.1097/j.pain.0000000000000747](https://doi.org/10.1097/j.pain.0000000000000747)

.... *“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

Winkler A, Auer C, Doering BK, Rief W. CNS Drugs. 2014 Sep;28(9):799-816. doi: 10.1007/s40263-014-0198-7. Drug treatment of primary insomnia: a meta-analysis of polysomnographic randomized controlled trials.

**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 .3 effect size - small effect  
(placebo controls)

Khan A, Fahl Mar K, Faucett J, Khan Schilling S, Brown WA

World Psychiatry. 2017 Jun; 16(2): 181–192. PMID: 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)

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- **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)

- Avouac J, Gossec L, Dougados M. Osteoarthritis Cartilage. 2007 Aug; 15(8):957-65. Epub 2007 Mar 29. Efficacy and safety of opioids for osteoarthritis: a meta-analysis of randomized controlled trials.
- Day RO, Graham GG, BMJ 2013 Jun 11; 346:f3195. doi: 10.1136/bmj.f3195. Non-steroidal anti-inflammatory drugs (NSAIDs).

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# Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain

## A Systematic Review and Meta-analysis

JAMA Intern Med. doi:10.1001/jamainternmed.2016.1251  
Published online May 23, 2016.

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 <sup>Krebs et al., 2017</sup>.)

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.

MacPherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34,000 treatments by traditional acupuncturists. *BMJ* 2001; 323:486-7.

Melchart D, Weidenhammer W, Streng A, et al. Prospective investigation of adverse effects of acupuncture in 97,733 patients. *Arch Intern Med* 2004; 164: 104-5.

Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed* 2009; 16: 91-7.

# 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. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>.

Rudd RA, Seth P, David F, Scholl L. [Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015](http://dx.doi.org/10.15585/mmwr.mm6550e1). MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm6550e1>.

### 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.”

# Comparing Side Effects/Risks

## 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.



Howard RL, Avery AJ, Slavenburg S, et al. Which drugs cause preventable admissions to hospital? a systematic review. *Br J Clin Pharmacol.* 2007;63(2):136-147.

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.

Bidaut-Russell M, Gabriel SE. Adverse gastrointestinal effects of NSAIDs: consequences and costs. *Best Pract Res Clin Gastroenterol.* 2001;15(5):739-753.

# Professional Guidelines



## National Pain Strategy

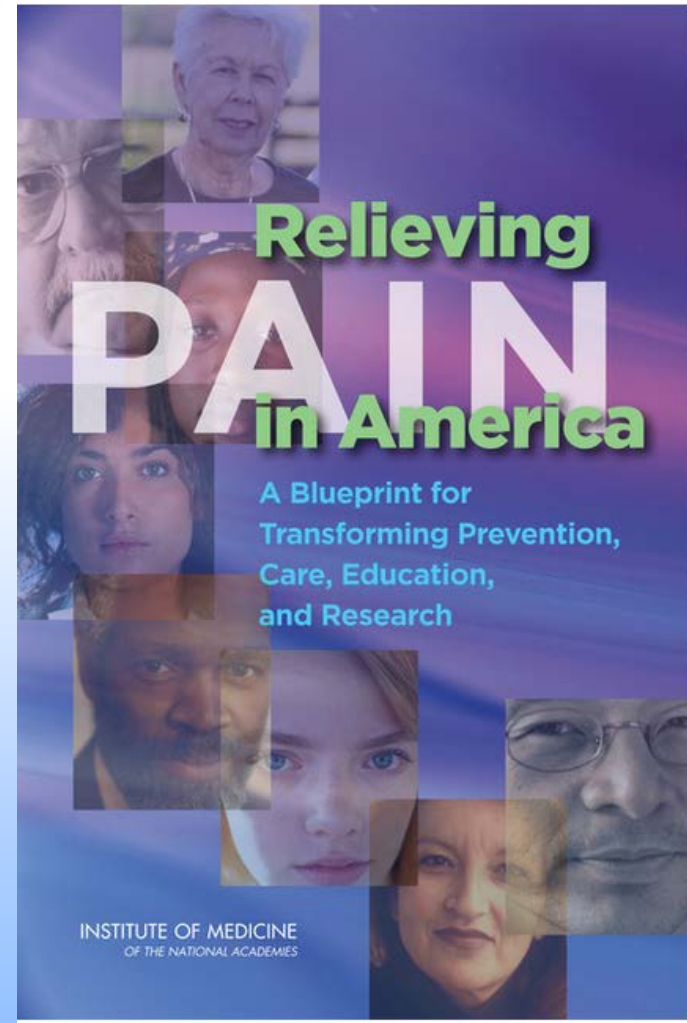
A Comprehensive Population Health-Level Strategy for Pain



American College of Physicians  
Leading Internal Medicine, Improving Lives



The National Academies of SCIENCES  
ENGINEERING  
MEDICINE



# *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 and 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.

# *Professional Guidelines*

## **FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain (May 2017)**

(Draft Revisions to FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids)

### **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”



Access restricted

# 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.**

Medicaid and most Vermont insurances do not cover acupuncture

Medical News & Perspectives

# As Opioid Epidemic Rages, Complementary Health Approaches to Pain Gain Traction

JAMA Published online November 2, 2016

Jennifer Abbasi

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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."



Berlin Wall - 1989

Barriers to Access  
"Tear down that wall!"

# *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:*

- *Tom Simpatico, Aaron French, Lindsay Parker, Kristina Valentine, Alexander Cavert, Carrie Barron, Gary Badger, Remy Coeytaux, Hugh MacPherson, Helene Langevin, Shawn Skaflestad, Rich Pinckney, Cara Feldman Hunt, Scott Strenio, Danielle Fuoco, Walter Ochs, Susan Whitney*
- *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*

# ***APPENDIX***



# Pharmaceutical effect size comparators

Effect size estimates for treating  
physical function:

Opioids for physical function .30 - small effect  
(placebo and wait list controls)

- Avouac J, Gossec L, Dougados M. Osteoarthritis Cartilage. 2007 Aug; 15(8):957-65. Epub 2007 Mar 29. Efficacy and safety of opioids for osteoarthritis: a meta-analysis of randomized controlled trials.

## Our acupuncture results:

- **Sleep Disturbance** 23 points (.64 effect size)
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- **Social Isolation** 8 points (.20 effect size)

# POPULATION

## 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 - 1<sup>st</sup> 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

# OUTCOMES - PROMIS

## Pain Intensity – Short Form 3a

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

In the past 7 days...		Had no pain	Mild	Moderate	Severe	Very severe
		1	2	3	4	5
PAINQU6	How intense was your pain at its worst?....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAINQU8	How intense was your average pain?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		No pain	Mild	Moderate	Severe	Very severe
		1	2	3	4	5
PAINQU21	What is your level of pain right now?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# OUTCOMES – PROMIS Pain Interference Short Form 8a

In the past 7 days...

		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
PAININ9	How much did pain interfere with your day to day activities? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ22	How much did pain interfere with work around the home?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ31	How much did pain interfere with your ability to participate in social activities?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ34	How much did pain interfere with your household chores?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ12	How much did pain interfere with the things you usually do for fun? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ36	How much did pain interfere with your enjoyment of social activities?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ3	How much did pain interfere with your enjoyment of life? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ13	How much did pain interfere with your family life?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

# OUTCOMES - PROMIS

## Fatigue Short Form 8a

**During the past 7 days...**

		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
HI7	I feel fatigued .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
AN3	I have trouble <u>starting</u> things because I am tired.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>In the past 7 days...</b>						
FATEXP41	How run-down did you feel on average? ...	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
FATEXP40	How fatigued were you on average? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

# OUTCOMES - PROMIS

Fatigue Anxiety and Depression Short Forms 4a

**In the past 7 days...**

		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
EDANX01	I felt fearful.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX40	I found it hard to focus on anything other than my anxiety .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX41	My worries overwhelmed me.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX53	I felt uneasy .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**In the past 7 days...**

		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
EDDEP04	I felt worthless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP06	I felt helpless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP29	I felt depressed .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP41	I felt hopeless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5



# OUTCOMES – PROMIS

Sleep Disturbance 4a and Social Isolation 4a

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
<b>In the past 7 days...</b>						
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing. ....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep20	I had a problem with my sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep44	I had difficulty falling asleep .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

		Never	Rarely	Sometimes	Usually	Always
UCLA11x2	I feel left out.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
UCLA13x3	I feel that people barely know me.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
UCLA14x2	I feel isolated from others .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
UCLA18x2	I feel that people are around me but not with me .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

# OUTCOMES — Physical Function 8b

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11	Are you able to do chores such as vacuuming or yard work?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA21	Are you able to go up and down stairs at a normal pace? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA23	Are you able to go for a walk of at least 15 minutes? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA53	Are you able to run errands and shop?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
					Quite a lot	
		Not at all	Very little	Somewhat		Cannot do
PFC12	Does your health now limit you in doing two hours of physical labor? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFB1	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA5	Does your health now limit you in lifting or carrying groceries?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA4	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

# Acupuncture needle vs. hypodermic needle

